

DEVELOPMENT OF A PATIENT REPORTED OUTCOME MEASURE ASSESSING LOWER LIMB JOINT FUNCTION

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by

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i. Abstract

Development of a patient reported outcome measure assessing lower limb joint function. Author: Trupesh Patel

Introduction and Aims:

Patient reported outcome measures (PROMs) are a way to measure health related quality of life. It is important that robust PROMs are developed so that disease states can be fully standardized and compared between patients. Within osteoarthritis, 4 PROMs are used commonly. Several qualitative limitations were identified that limit the clinical suitability of the PROM. We aim to begin the process of developing a new PROM to assess lower limb joint function using osteoarthritis as the model.

Methods:

A mixed methods approach was used using semi-structured qualitative interviews (for patient participants) and the first round of a Delphi analysis (for expert participants) to generate factors that affect lower limb joint function. Only patient participants were used to generate activity or participation restrictions. Content analysis was used to analyze the data. These concepts were then converted into items to be used in the novel PROM.

Results:

We have created a bank of items that holistically assess lower limb joint function.

Conclusion:

This study has generated novel and potentially important contributions to the field of orthopaedic surgery. This has formed the initial stage of developing a PROM. Future research should aim to continue the development and validation process to create a final version that is suitable for clinical practice.

ii. Abbreviations

AOS - Ankle Osteoarthritis Index

AOFAS - American Orthopaedic Foot and Ankle Society

CI = Confidence interval

FFI – Foot Function Index

HAQ – Health assessment questionnaire.

HR-QoL – Health related quality of life

ICF - International Classification of Functioning, Disability and Health

MHI – Mental Health Inventory

MOS – Medical Outcomes Survey

OHS – Oxford Hip Score

OKS – Oxford Knee Score

Pre-op = Pre-operative

PROM(s) – Patient reported outcome measure(s)

PCT – Primary care trust

QoL = Quality of Life

WOMAC – Western Ontario McMaster Universities Osteoarthritis Index

1.0 Background

1.1 Quality of life

1.1.1 Introduction

Within medicine, quality of life issues have received more attention after the World Health Organisation (WHO) defined health as ‘a state of complete physical, mental and social well-being, and not merely the absence of disease’¹. This definition holistically captures an individual’s health status and thus will include aspects like income, freedom or quality of environment². Health-related quality of life (HR-QoL) is a “multidimensional construct comprising (at least) physical, psychological and social well-being and functioning as perceived by the individual”³.

1.1.2 Why measure health-related quality of life?

Generally, measurement of the various domains of HR-QoL are crucial to provide accurate assessments of the utility or flaws of healthcare interventions on patients⁴. Crucially, it focuses on the impact of their condition and treatment on their lifestyle, which importantly answers the question ‘whether a treatment leads to a life worth living.’ This information is not only crucial for the care-giver but also to purchasers of healthcare, whom must know the efficacy of treatments⁵. Outcomes can be measured at various levels of a 4-stage model: “basic science (e.g. chemistry), basic biology (e.g. immunology), clinical study (e.g. pharmacology) and personal outcome (e.g. rehabilitation). At each stage the phenomenon is studied through different facets; ‘the molecule, the cell, the organ, the disease and the patient’. Success in addressing for example a biological outcome may not translate into benefits at other stages in the model⁶. There may be a disconnection between these processes, which explain why existing measures of disease activity often correlate poorly with a patient’s wellbeing². It is argued that an improvement of HR-QoL should be the endpoint goal of healthcare, which has personal and emotional meaning to the patient rather than other parameters of interest to the clinician⁶. However, for a comprehensive assessment, measurement of all parameters of disease including patient perspective should be obtained⁵.

1.13 Who should assess health-related quality of life?

Patients can be assessed by history taking and examination and/or by outcome measures, which can be objective and/or subjective. Subjective measurements rely on the patient to offer an estimation of their HR-QoL, whereas objective measurements do not⁷. Historically, clinicians have provided assessments of outcome by examination or other measurement⁸. While this was previously adequate, as more research was done, the patient perspective had been considered because patients and doctors often significantly disagree about health status⁹⁻¹². Clinicians often fail to recognize or under-report functional limitations that were described by patients¹³. There seems to be a systematic bias where clinicians under-report symptoms consistently¹¹. Patients will report their functional disabilities to their clinicians, as this is their perspective of their disease. Clinicians will subsequently under-report these limitations when asked to report the difficulties their patients described¹³. Age, sex, socioeconomic status, marital status and diminishing health status have significant correlation with the variability between the patient and clinicians opinion⁸.

This misrepresentation of a patient's health related quality of life can have implications on their care. One study concluded that under-reporting of pain resulted in inadequate prescriptions of analgesia and an underreport of functional status caused more dissatisfaction among patients¹³.

There is strong evidence to suggest measurement of HR-QoL should be done by self-report and not by their care-giver. Thus there has been a shift of clinician related outcome to PROMS during the last decade¹⁴.

1.2 Patient Reported Outcome Measures

1.2.1 Introduction

Patient reported outcome measures (PROMs) are standardised, validated questionnaires completed by patients to measure their perceptions of their own functional status and wellbeing¹⁵. The idea started more than 100 years ago but began to become popular around 25 years ago with the agendas of improving

care and comparing outcomes of treatment^{16, 17}. Standardised questionnaire refers to the ability of a questionnaire to have a set amount of questions, that are phrased the same way for all participants¹⁸.

1.2.2 Types of Patient Reported Outcome Measures

There are several types of outcome measures; 1) disease-specific 2) site/region specific 3) dimension specific 4) generic 5) summary items and 6) individualised. PROMs can be specific to one category or overlap, for example the Oxford Hip Score which would be considered a disease and site-specific PROM^{17, 19}.

- 1) Disease specific PROMs are related to a single disease, for example the Aberdeen Varicose Vein Questionnaire²⁰. These PROMs are more likely to detect clinical changes because they have been developed and validated for that disease. The items should all be relevant to that disease group and contain minimal items that are irrelevant to that population²¹. Thus, acceptability of the PROM is likely to be high. However, it is not possible to administer to those without the disease, as it may not be validated for that population. Therefore, health status scores cannot be compared between disease and non-disease groups, which may be useful in health economics. The focused nature of the PROM may prevent the detection of side effects or new effects of treatment that may have been possible with a generic PROM²².
- 2) Site/region-specific PROMs aim to measure HR-QoL in a single region of the body, for example the Liverpool Elbow Score²³. This is particularly relevant for some surgical specialties like orthopaedic surgery which are region based. For example, asking about pain due to osteoarthritis would not help to ascertain the pain levels in a specific joint that concerns the patient²¹. Their disadvantages are similar to disease specific PROMS.
- 3) Dimension specific PROMs measure only one aspect of HR-QoL, for example the Hospital Anxiety and Depression Scale^{24, 25}. Dimensions can

include physical function, symptoms, emotions, functions, well-being and satisfaction of treatment etc. They are advantageous in that a very detailed item list can be used to assess one aspect of health, in comparison to other PROMs where it may be done superficially²¹.

- 4) Generic PROMs aim to be as comprehensive as possible to measure a patient's HR-QoL in addition to being validated to a heterogeneous sample of the population. They will often contain many dimensions to capture the patient perspective holistically²¹. The Short-Form 36 is an example²⁶. The main advantage of generic PROMs are that they can be used for a wide range of health problems. Therefore, they can be used to compare different treatments in different patient groups. Their holistic assessment of health means that they have the potential to observe the influence of co-morbidity on health and any unpredicted effect of disease or treatment on health. Nevertheless, the broad applicability means they are potentially less responsive to clinical change²².
- 5) Summary items are very short PROMs that aim to summarise QoL within a few questions. They often contain items which allow the respondents to assess their health compared to a previous point in time, which can provide useful information for their healthcare team²¹. For example, the General House Survey for England and Wales. Summary items are short and require the least effort from the respondent, which can be hugely advantageous. However, the brevity of summary items limits the conclusions that can be drawn from it and therefore the usefulness of the PROM²².
- 6) Individualised measures are outcome measures where the responder can comment, choose or create the most relevant issues to them²¹. The Patient Generated Index is an example²⁷. They have a high content validity, as the items are patient generated by the individual. They often have to be constructed and completed in front of a caregiver, as the

items may not be relevant or amenable to change by treatment. This may affect its feasibility to be used in clinical practice²².

1.2.3 Applications of PROMs

PROMs have been developed for a range of applications. Clinical trials and other medical research require methods of measuring outcome²⁸. PROMs provide a valid, reliable and standardised method of measurement to facilitate comparison longitudinally between participants or groups of participants. Additionally, Good Clinical Practice and regulatory bodies expect clinical trial researchers to use PROMs within their study³. The Department of Health has required the routine use of PROMs, for all NHS patients, before and after receiving surgery. Specific PROMs are used for varicose vein surgery, hernia repair surgery, hip replacement and knee replacement surgeries.

The Kings Fund Organisation suggests a plethora of uses for PROMs to inform patients and to give them choice in the NHS. PROMs data could assist patients to decide where and from whom to receive treatment and predict the likely benefits of treatment to their own case. This is important, as since 2008 the NHS have offered patients an 'open choice' to select their providers in England. Previously, this information has been presented as indicators of negative outcomes like hospital infection rates or post-operative mortality. PROMs data could inform clinicians and patients, with making informed decisions about their treatment. For example, a study carried out by Spire Healthcare showed how PROMs could be used pre and post-operatively for a hip replacement surgery. The data showed the average physical functioning scores before treatment, after treatment and people of similar age in the UK population. It clearly showed patients that hip replacement results in better physical functioning but not the same as those without disease matched for a similar age. This could help inform patients deciding on whether they would like hip replacement surgery. As the NHS accumulates more information from PROMs, the potential to predict the benefits of a treatment for a specific patient could be established when adjusting for age, sex, pre-existing condition and so on.

PROMs data can also be used to manage clinical quality in hospitals. Data can be used to monitor the quality of care being delivered and facilitate discussion between managers and clinicians. Combined with hospital episode statistic data, PROMs allow for much more in-depth analysis of variation in HR-QoL between trusts. The data could be used to identify poorly performing teams or clinicians and identifying and sharing best practice²⁹.

There is a large scope for using PROM data in commission care. GPs and primary care trusts (PCT) can use PROMs data in various ways to assess value-for-money and performance. For example, specifying minimum change on PROMs required to their contracts with certain providers or incentivizing providers to improve care by linking payment to the change in score of the PROM. PCTs can also compare their data with others identifying which PCT's are most effective in commissioning care²⁹.

PROMs data can also be used in clinical decision-making. Clinicians can look at PROMs data before treatment to suggest appropriate treatment options with them. They can be used as part of routine patient assessment and provide baseline information about their HR-QoL. Used longitudinally, the data can then provide information on effectiveness of treatment or disease progression. PROMs can highlight problems that the patient experiences, that may not have been thought about by the patient's own suggestions. PROMs may also be used to aid decision making in the referral process, where a cut-off score can be used²⁹.

Lastly, they provide another indicator of health state among various other tests e.g. biochemistry or radiology⁸.

1.3 Models Underpinning PROM design

1.3.1 International Classification of Functioning, Disability and Health

The International Classification of Functioning, Disability and Health (ICF) is a model created by the World Health Organisation that provides a framework and

benchmark to describe health states³⁰. Figure 1 shows the various identified concepts and the relationships between each other. Table 1 defines the terms used within the model. Among the need for such a classification in health planning and economics, it was established that there was an increased recognition to measure levels of functioning and disability so that appropriate health management decisions can be made to improve a person's quality of life. The utility of existing PROMs can be enhanced by including all aspects of the model within the items. For example, the certainty of an effect of intervention is unknown with PROMs that only ask about participation and activity levels. This is because environmental or personal factors may have changed during the administrations of the PROMs. PROMs should comprehensively and holistically look at factors mentioned in the model and be able to measure them. This would allow healthcare providers to discern whether any improvement in HR-QoL is due to disease/intervention or other factors.

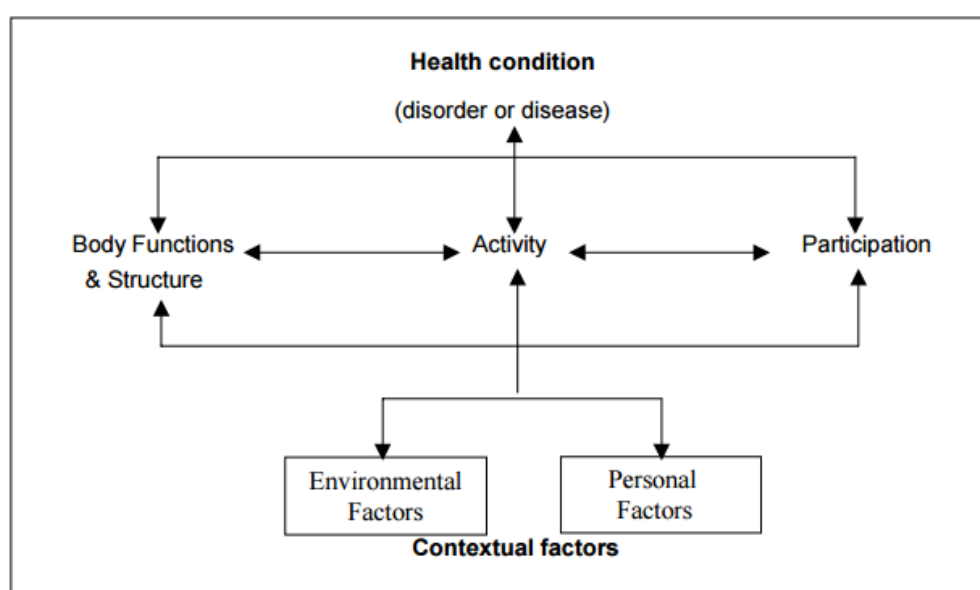


FIGURE 1- MODEL OF DISABILITY FOR ICF³⁰

Body functions	The physiological functions of body systems (including psychological functions).
Body structures	Anatomical parts of the body such as organs, limbs and their components.
Impairments	Problems in body function and structure such as significant deviation or loss.
Activity	The execution of a task or action by an individual.
Participation	Involvement in a life situation.
Activity limitations	Difficulties an individual may have in executing activities.
Participation restrictions	Problems an individual may experience in involvement in life situations
Environmental factors	The physical, social and attitudinal environment in which people live and conduct their lives. These are either barriers to or facilitators of the person's functioning.
Functioning	Is an umbrella term for body function, body structures, activities and participation. It denotes the positive or neutral aspects of the interaction between a person's health condition(s) and that individual's contextual factors (environmental and personal factors).
Disability	Is an umbrella term for impairments, activity limitations and participation restrictions. It denotes the negative aspects of the interaction between a person's health condition(s) and that individual's contextual factors (environmental and personal factors).

TABLE 1 – ICF DEFINITIONS³⁰

Many instruments used in orthopaedic literature aim to address these domains but lack a theoretical framework on which it is based. There is no gold standard for reference³¹. The ICF have devised a core set of structures, bodily functions, activities, participations and environmental factors that are proposed to be an “internationally-accepted and evidence based” structure to understanding the typical spectrum of problems a patient with osteoarthritis might have³² (Appendix A). It contains various codes underlying the different categories of the model. For example, under ‘activities and participation’ it contains walking and dressing. PROMs can be linked to these concepts to understand how the items correlated to this model.

1.3.2 Discriminative, Predictive & Evaluative Indices

Kirshner and Guyatt were pioneers in the field of health measurement as they created distinctions between the uses of health indices. They described 3 distinct uses; 1) evaluative 2) predictive and 3) discriminative. Evaluative indexes are used to measure the change of the measured construct over time. Predictive indexes classify individuals based on predefined measurements when there is a gold standard available. This is useful for screening of diagnostic purposes. Discriminative indexes distinguish between individuals on a construct that has no external criterion or gold standard³³.

1.3.3 Constructs

Constructs can be defined as “phenomena that are real and exist apart from the awareness and interpretation of the researcher and the persons under study³⁴”. Constructs are designed to be reflective of real life phenomena and thus not measure the phenomena itself. The phenomenon that the construct seeks to measure can be observable or non-observable. Observable constructs can be measured directly for example the pH of blood. In contrast, all non-observable constructs relate to perceptions, for example, patients own self-report of their health status³⁴. Factors or manifest variables can be referred to as denominations of the construct, for example activities of daily living or participation activities²⁸.

1.3.4 Formative and Reflective factors

Fayers et al introduced the idea that within quality of life assessment, items can be categorised into two types of indicators; causal and effect³⁵. These terms have now been replaced with formative and reflective factors respectively³⁶.

Formative factors refer to variables that cause a change in the construct, for example it is hypothesized that an increase in body mass index (BMI) may cause reduced function in osteoarthritic patients²⁸ (Figure 2). Causal (formative factors) do not imply they have a causal relationship. It merely implies that the variable has an impact on the construct^{37, 38}. Reflective factors, which form most of quality of life questionnaires consists of measures that would change if the construct changes. For example, if there is a change in function due to a bigger BMI it is anticipated that a person's ability to walk will be affected (Figure 2).

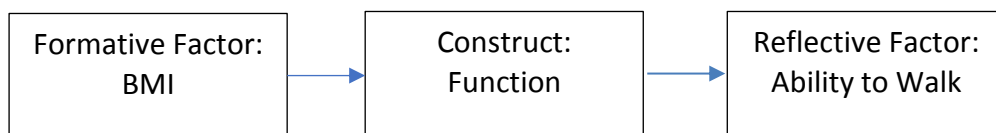


FIGURE 2 – RELATIONSHIP BETWEEN FORMATIVE AND REFLECTIVE FACTORS

There are several key differences between the factors. Reflective factors are manifested by the same construct and thus reflect the construct. They are interchangeable, and addition or removal of any items do not change the construct. Formative factors define the construct and thus they may not share a commonality. Therefore, they are not inter-changeable with each other. The addition or removal of items would change the definition of the construct³⁶. Conversely in reflective models there, should be high level of inter-relatedness between variables as they are reflections of the construct. There may even be a negative relationships between the variables³⁹. Hence, why standard measures of reliability like Cronbach alpha or factor analysis cannot be used on formative models. Empirical testing cannot be performed on formative models, there is no universally accepted criteria for assessing the reliability or validity of the formative indicators³⁶.

1.3.5 Measurement properties

The Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) is an enterprise that developed a comprehensive list of measurement properties which all PROMs should ideally have⁴⁰.

The COSMIN initiative invited many experts from around the world to participate in a Delphi analysis. 91 members in the field of psychology, epidemiology, statistics and clinical medicine whom also had at least 5 publications on health status measurement participated in the scheme. The authors have clearly selected an expert panel that covers all areas of healthcare measurement⁴¹. The checklist contains 4 domains to assess various measurement properties. Within those measurement properties, there are different aspects that should be measured. A structural outline and definitions are presented below.

1. Reliability
 - a. Internal consistency
 - b. Measurement error
2. Validity
 - a. Content validity
 - i. Face Validity
 - b. Construct validity
 - i. Structural validity
 - ii. Hypothesis testing
 - iii. Cross-cultural validity
 - c. Criterion validity
3. Responsiveness
4. Interpretability

- 1) Reliability is “the extent to which scores for patients who have not changed are the same for repeated measurement under several conditions: e.g. using different sets of items from the same health related-patient reported outcomes (HRPRO) (internal consistency); over time (test-retest); by different persons on the same occasion (inter-rater);

or by the same persons (i.e. raters or responders) on different occasions (intra-rater).”

- a. Internal Consistency is “the degree of the interrelatedness among the items.”
- b. Measurement error is “the systematic and random error of a patient’s score that is not attributed to true changes in the construct to be measured.”

2) Validity is “the degree to which an HR-PRO instrument measures the construct(s) it purports to measure.”

- a) Content validity is “the degree to which the content of an HR-PRO instrument is an adequate reflection of the construct to be measured.”

- i) Face validity is “the degree to which (the items of) an HR-PRO instrument indeed looks as though they are an adequate reflection of the construct to be measured.”

- b) Construct validity is “the degree to which the scores of an HR-PRO instrument are consistent with hypotheses (for instance with regard to internal relationships, relationships to scores of other instruments, or differences between relevant groups) based on the assumption that the HR-PRO instrument validly measures the construct to be measured.”

- i) Structural validity is “the degree to which the scores of an HR-PRO instrument are an adequate reflection of the dimensionality of the construct to be measured.”

- ii) Hypothesis testing is the “item construct validity.”
- iii) Cross cultural validity is “the degree to which the performance of the items on a translated or culturally adapted HR-PRO instrument are an adequate reflection of the performance of the items of the original version of the HR-PRO instrument.”
- c) Criterion validity is “the degree to which the scores of an HR-PRO instrument are an adequate reflection of a ‘gold standard.’”
- 3) Responsiveness is “the ability of an HR-PRO instrument to detect change over time in the construct to be measured.”
- 4) Interpretability is “the degree to which one can assign qualitative meaning - that is, clinical or commonly understood connotations – to an instrument’s quantitative scores or change in scores”^{40, 41}.

1.4 Burden of Osteoarthritis

Osteoarthritis is the most common form of arthritis affecting 7.3 million people in England and representing 33% of the population over 45. There are also 1.76 million people (24%) that have osteoarthritis in one or more joints. It is a clinical syndrome of joint pain with functional limitations causing a decrease in quality of life. It accounts for more people having difficulties walking and climbing stairs than any other disease, where 25% of people cannot adequately perform their activities of daily living. It also has considerable impact on society including impact on the health services⁴².

1.5 Physical function

Physical function is defined as the ability to undertake various physical tasks ranging from basic activity of daily living to strength and endurance activities.

Lower limb function concerns itself with mobility contrasted to dexterity (upper limb) and axial function (neck and back)⁴³.

2.0 Literature Review

The aims of this review are to firstly identify the development of 4 commonly used outcomes measures used to assess physical function in lower limb arthritis and secondly to identify the patients' perspective in using them.

2.1 Oxford Hip Score

2.1.1 Development

The Oxford Hip score (OHS) was developed and validated in 1996 by a research team at the University of Oxford and Nuffield Orthopaedic Centre (appendix B)⁴⁴. Previous scores have used clinical and radiological information to assess the patient's health status. This is inadequate because patients and surgeons' opinion of their health status differ. During this period, it was accepted that a methodology that incorporates patient's opinion would be reliable and valid way of assessing health outcomes. The authors have looked at previous questionnaires and concluded that they are long and include items that may not be relevant to a specific problem. Thus, they may be insensitive to clinical change and thus unacceptable for routine use.

The authors interviewed 20 patients that attended an outpatient clinic. They were asked to comment on the problems they had incurred because of their hip problem. They looked at other established questionnaires to generate items; Harris Hip Score was one of them. 20 items were used. A new set of 20 patients were asked to complete 2 copies of this questionnaire; one to answer the questions and the second to be used as a feedback mechanism to assess the quality of the questionnaire and commentary of any hip problems not addressed by these items. These were returned using a franked envelope. 2 more iterations of this process occurred until the final questionnaire was approved. The questionnaire was arranged with 12 items spanning a 5-point Likert-type scale from least to most difficulty with a number from 1-5 associated with each to add a qualitative value to the answers. A sum of the total scores can be calculated to

give a score out of 60, where 60 indicated most difficulties and 12 (least difficulties)

2.1.2 Patient Perspective

A key study that examines the patient perspective using the OHS was conducted by Wylde et al¹⁴. Patients recruited between April 2005 and May 2005 at an orthopaedic pre-op clinic were given the OHS. The authors anticipated that this sample of patients would not have had the questionnaire administered before thus will be unfamiliar with the presentation and content. Patients were also recruited from January 2005 to May 2005 whom attended the clinic for their 12-month follow-up after having total hip replacements. Lastly, patients who had an IPS Stem between 1997 and 2004 were also administered the questionnaire as part of another study. All patients were under the care of one consultant orthopaedic surgeon. The participants were asked NOT to annotate their copy of the questionnaire. The authors then reviewed each questionnaire for comments.

Overall 276 patients completed the questionnaire. 17% of the patients commented on the quality of the score. 29% of comments regarded question clarity. Firstly, patients noted that there was difficulty in ascertaining whether the question asked for their level of disability when either using assistive devices or not. For example, item 7: “have you been able to put on a pair of socks, stockings or tights,” has caused the most confusion as patients do not know whether to answer for example with or without a shoe horn. Clarity was also an issue with item 5: “for how long have you been able to walk before pain from your hip becomes severe (with or without a stick)? This similarly was confusing as patients will experience varying amount of pain with or without a walking stick and thus is ambiguous. In this study, it was found that patients wrote down two answers to reflect the two different levels of disability. This results in an uninterpretable total score. The pain question causes patients frustration as the cognitive process of trying to sum up their last 4 weeks pain level is unreasonable to sum up on one question. The nature of osteoarthritic pain is dynamic and the use of “average” does not clarify the patients on what is being

asked. There is also an issue of asking irrelevant questions. For example, the question regarding climbing stairs would cause confusion due to misinterpretation. Some patients find that climbing stairs backwards would cause less difficulty than doing so in the normal way. They would not know what option to choose. Item 3 reflects on a patient's ability to get in and out of a car. Similarly, this causes an issue if the patients do not use a car or misunderstands the concept, for example not equating a taxi with a personal car. To reiterate, the OHS is a site and disease specific PROM. However, patients have reported a crucial failing. They fail to distinguish how their pain from their hip is different to any of their other co-morbidities. It has been found that the effect sizes are larger in patients with unilateral hip OA compared to patients with other functional-limiting co-morbidities. This goes against other studies that suggest the OHS is not influenced by other co-morbidities. Patients with bilateral hip problem report that the questionnaire only looks at one joint and thus not a useful tool to ascertain their perspective. Lastly, the question regarding putting on a pair of socks, stocking or tights confuses patients as they think it is asking 3 separate questions in one. Women will have more trouble putting on a stocking than a sock. The authors suggest that items should be rated in terms of importance, thus giving less weight to aspects that do not matter e.g. climbing stairs in bungalow-home owners, which allows users to state that this, This avoids a substantial problem that most PROMS have; relevancy of items¹⁴.

Similar to the previous study, the authors also look at patient experience in filling out the questionnaire⁴⁵. The sample was taken from July 2007 to February 1999 and patients were selected from pre-op clinics for total hip replacements. Patients were interviewed at their homes at baseline and four months after the operation. Patients completed this from 2 – 15 minutes and required varying levels of assistance for example having family or a staff member present. Patients reported that they could have placed an answer in 2 different boxes for the same question due to ambiguity in the question. Specifically, there were problems with item 2 and 4. There's no clarification to whether aids are to be

included, for example use of a long-handled brush. Thus, it would be hard to discern differences in function by the clinician.

Item 6 proved difficult as the responses were confusing. Patients could not equate answer 1 “no pain” and “more than 30 minutes.” They were perceived as mutually exclusive answers. Answer 5 “not at all-pain severe on walking” could not be discerned from answer 1. This resulted in patients spending more time thinking about the question itself rather than the answer. Items 1 and 2 caused confusion as patients doubted the ability of the question to accurately measure their pain levels. Pain could be tolerated by using coping strategies or interventions like pain killers. Similarly, for the question regarding pain at night, pain killers could modify the answer and thus questions should be clarified. This resulted in patients supplementing their answers with written answers. Lastly, patients find that they cannot discern their co-morbidities impact to their activities/participation. For example a patient who could decide whether their ability to walk up and down stairs was due to their angina or due to their osteoarthritis⁴⁵.

2.1.3 ICF component analysis

According to categorisation of ICF components, the OHS was linked to bodily structure, bodily functions, and participation and linked to environment. Structures were linked to structures of the lower extremity. Body functions examined were: sleep functions, sensations of pain, gait pattern function and sensations related to muscles and movement functions. Activities and participation: changing a basic body position, walking, moving around, using transportation, washing oneself, acquisition of goods and services, doing housework and remunerative employment. Environmental factors: products and technology for personal indoor and outdoor mobility and transportation³¹.

2.2 Oxford Knee Score

The Oxford Knee Score (OKS) has 12 items. 5 items measure the construct of pain and 7 measuring function (appendix C)⁴⁶. The score ranges from 12 (best) to 60(worst). It is widely used in the National Joint Registry and in cohort studies. However, there is confusion as some surgeons have found the original method of scoring unintuitive and have modified the scale to run from 0 (best) to 48 (worst)^{47, 48}. It has been designed to measure outcomes in total knee replacements⁴⁹.

2.2.1 Development

The authors interviewed 20 osteoarthritic patients whom attended an outpatient clinic. They were all for consideration for a TKR. However, the authors did not describe any other data to determine the generalisability of the sample. The participants were asked “how they experienced and reported problems with their knees.” A 20-item questionnaire was constructed which was administered to 20 new participants. They were instructed to complete the questionnaire at baseline and at 1 day after using a franked envelope and provide feedback in addition to addition knee related problems. The authors modified items that were difficult for patients and not considered reproducible. They repeated this process twice. The authors note that appearance of the PROM was also considered⁴⁶. Originally it was validated with 117 participants: 66 women and 51 men. 114/117 had clinical details available, were 98/114 had advances primary osteoarthritis, 9/114 has secondary osteoarthritis (mostly osteonecrosis or previous fractures, 9/114 had inflammatory arthritis, 8 other patients with diseases like gout, Paget’s disease and haemophilia⁴⁶.

2.2.2 ICF component analysis

According to categorisation of ICF components, the OKS was linked to bodily structure, bodily functions, and participation and linked to environment. Structures were linked to structures of the lower extremity. Body functions examined were: sleep functions, sensations of pain, stability of joint function, gait pattern function. Activities and participation: changing a basic body position,

walking, moving around, using transportation, washing oneself, acquisition of goods and services, doing housework and remunerative employment.

Environmental factors: products and technology for personal indoor and outdoor mobility and transportation³².

2.2.3 Patient Perspective

Question 7 refers to kneeling abilities. This proved difficult as patients have often been instructed by their clinician to not kneel down. It is noted that the authors recommend the patient to estimate what they answer may be, highlighting an example of the inappropriate use of PROMs⁴⁷. Patients have also been found to annotate their questionnaire. This could be interpreted as a failure of understanding, scoring, relevance or other issues⁴⁸. “How would you describe the pain you usually have from your knee” and “How much has the pain from your knee interfered with your usual work (including housework)” were often left blank because patients needed clarification of the content⁵⁰. The item referring to kneeling was also poorly understood due to various external factors for example patient apprehension or restriction of that activity based on their surgeons’ advice⁵¹. The score also reflects a time when TKA was done in a more elderly and sedentary population, the current questions may not be relevant to a population who are younger⁵².

2.3 The Western Ontario and McMaster Universities Arthritis Index

The Western Ontario and McMaster Universities Arthritis Index (WOMAC) is a PROM designed to assess pain, stiffness and physical function with patients with hip and/or knee OA⁵³. It has 24 items divided into 3 scales (pain – 5 items, stiffness – 2 items and physical functioning). Please find this in Appendix D

2.3.1 Development

The development of the index was described as part of an MSc thesis. This was not available for viewing despite repeated attempts to contact the author through the website www.womac.org.

2.3.2 Patient Perspective

The WOMAC does not take into consideration of use of aids and devices¹⁴. This causes participants to estimate a level of disability based on their own personal use or disuse of assistive devices. This may not be suitable if a repeated administration of the outcome measure is necessary, as a change in assistive device use would confound results. The WOMAC items have been found to be influenced by other comorbidities like low back pain⁵⁴. The WOMAC also contains some unimportant, irrelevant questions to some people with OA, which was reflected in a low response rate⁵⁵. It was found that under observation, 23.3% of responders required assistance when filling it in⁴⁷.

2.3.3 ICF component analysis

According to categorisation of ICF components, the WOMAC was linked to body functions: sleep, sensation of pain and activity and participation: changing basic body position, maintain basic body position, walking, moving around, washing oneself, toileting, dressing, acquisition of goods and services and doing housework³¹.

2.4 The Short Form 36

The SF-36 is an outcome measure containing 36 questions spanning 3 overarching aspects of health: functional ability, wellbeing and overall health (appendix E). These are associated with 8 domains as tested by the outcome measure; physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. Domains that were not chosen included health distress, cognitive functioning, sexual functioning, family functioning and sleep adequacy²⁶. The SF-36 has scores from 0 – 100 where 0 indicates a worse health state than 100⁵⁶.

2.4.1 Development

The development of the SF-36 was documented in its user manual⁵⁶.

The conceptual origins of which the subscales were derived from are outlined in table 2.

Domain	Items obtained from:
Physical functioning	Canadian Sickness Survey Index of Well-Being Functional Status Index Functional Limitations Index Functional Status Assessment
Physical Role Functioning	Sickness Impact Profile
Bodily Pain	Wisconsin Brief Pain Questionnaire
General Health Perceptions	National Health Interview Survey Health Perceptions Questionnaire
Vitality	General Well-Being Schedule
Social Role Functioning	MOS-FSWBP
Emotional Role Functioning	Sickness Impact Profile
Mental Health	General Well-Being Schedule Mental Health Inventory

Table 2 – Conceptual originals of the SF-36

2.4.1.1 Physical Functioning

All ten items from the Medical Outcomes Survey (MOS) physical functioning scales were used without any changes being made to the content. The scaling options were revised to a 3-level continuum response scale because it was determined that it was more useful to assess whether movement activities are performed with difficulty or without difficulty compared to an increased precision of response e.g. a 5 or 7-point scale.

2.4.1.2 Physical Role Functioning

The SF-36 contains 4 out of the original 11 items on the MOS long form. They cover an array of lifestyle limitations that include work and other activities, broadening

the applicability to a wider age range. The questions also create a distinction between role limitations due to physical health and due to mental health, which is covered under another domain. Version 2 of the SF-36 now have a 5-level response compared to a binary “yes/no” response in version 1.

2.4.1.3 Bodily Pain

2 items taken from the SF-20 outcome measure have been chosen to assess bodily pain; intensity and functional impact of pain. The latter item was chosen because it had the highest prediction for overall score on pain in the MOS outcome measure ($r=0.84$).

2.4.1.3 General Health Perceptions

The SF-36 contains 5 items related to general health. One is a widely used generic question rated from excellent to poor and the other 4 come from the Health Perceptions Questionnaire. These questions derive content from the domains of: current health, resistance to illness and health outlook.

2.4.1.4 Vitality

Vitality concerns itself with energy level and fatigue. 4 Items were derived from the Mental Health Inventory (MHI)

2.4.1.5 Social Role Functioning

This domain normally reflects the quantity and quality of social activities performed by respondents. However, in the SF-36 2 items were derived from the MOS which assess health impact on social activities

2.4.1.6 Emotional Role Functioning

This domain normally reflects the quantity and quality of social activities performed by respondents. However, in the SF-36 2 items were derived from the MOS which assess health impact on social activities.

2.4.1.7 Mental Health

A five-item version of the MHI was constructed. These 5 items best predicted the overall score of the MHI. These questions reflect anxiety, depression, loss of behavioral/emotional control and psychological wellbeing.

2.4.1.8 Self-Evaluated Transition

The SF-36 also contains a 6th general health question relating to the amount of change in health respondents have experienced over a year.

2.4.2 Patient Perspective

Participants were invited to a qualitative interview session to establish the extent to which the questions are understandable. 56 patients who have been referred for physiotherapy or occupation therapy rehabilitation (mean age = 77yrs) were interviewed face-to-face twice: once at baseline and once at 6 months. Interviews were transcribed and thematically analysed. Physical functioning and general health subscales' views were studied.

The respondents identified several problems with the items addressing physical functioning. Double-worded questions are difficult for participants to answer, for example, "Does your health limit you in these activities; Can you bend, kneel or stoop." It demands an inappropriate level of responsibility to formulate an answer. Some may answer according to one of the activities on the list or some may average out their answers across what they perceive their disability is or may select the 'middle' option due to outright confusion. Most often the participants selected 'limited a little,' which is the middle scaling option.

"Can you walk more than a mile?" This questions typically exemplifies the use of unfamiliar terms. Generally, phrases which appear useful to outcome measure researchers do not have utility within the patient population subgroups. Participants found that 1 mile was not relatable as they often measured distances in comparison to landmarks. In an unassisted administration of the Sf-36 participants would have to guess the best answer in response to the question. This

reduces the reliability of the outcome measure. Regarding the same question, participants found that the question was too vague and did not give context to the scenario. For example, it would have more useful to ask about walking up a hill, on the street or walking to the shops etc.

“...Lifting or carrying goods,” similarly presented an issue of vagueness. Participants did not know if it was carrying light goods for example for a short trip to the local shops or a heavy weekly shop from a supermarket.

“...Bathing or dressing yourself.” Some participants took this question literally and assumed it was only to do with having a bath rather than any other methods of personal hygiene like showering.

There are numerous examples of irrelevant questions. One example, “...walking more than a mile.” Some participants chose not to perform that activity and thus without an option of ‘I don’t know’ or “irrelevant,” the respondent is forced to choose a response that fits in line with the other answers they have given for other questions. In contrast, the responder may leave the question blank, affecting the scoring options and interpretation of the summated score. The other effect of irrelevant questions related to the motivation of the responder to complete the outcome measure. They may feel less inclined to put a genuine effort to answer the question which can lead to irritation and boredom leading to withdrawal from the process.

“Can you climb a flight of stairs?” This question illustrates relativism and the idea that patient’s health changes over time changes and thus their judgement and conceptualisation will alter over the course of their disease. In relation to outcome measure’s this results in patients adapting their lifestyle to cope with the disease and thus will change the level of perceived disability. For example, a participant commented that with a coping mechanism like breathing in and out on every step, climbing stairs becomes a lot easier. The authors concluded it is important to

understand the extent to which these disability-modifying behaviors are used on the outcome measure.

Due to the generic nature of the questions, there is an assumption that diseased participants are expected to be in the range of normative physical function values as the public. The 3 tier scaling options means a significant floor effect will be present and thus insensitive to change. This could be due to a lack of patient involvement during the development of the outcome measure⁵⁷.

A study where patients aged 65 or older (n = 45) referred to occupational therapy or physiotherapy were asked to complete the SF-36 via a postal administration at 3 months' post baseline administration. On return of the SF-36, 5 participants did not respond to question 4, which refer to role-limitations. It is suggested that the wording of the question is inappropriate as they are not phrased as problems. Additionally, the use of the word "work" in question 4a is misunderstood by the retired population, who assume its definition is occupational work. One participant commented on the question and wrote "I am retired-don't work." Question 3a "...vigorous activities such as running, lifting heavy objects, participating in strenuous sports" caused difficulty because it was inappropriate for the elderly population tested upon.

A questionnaire evaluation was also performed and it was shown 28% had no problem filling in the questionnaire, 47% said they had some difficulties and the remaining 24% said they found all aspects of the questions difficult. 64% of responders also needed assistance from a relative or friend to help with interpretation.

There were many unsolicited remarks present on the SF-36 upon return. One participant commented on the irrelevance of mentioning "housework" within multiple questions as she stated, "home help does housework." As mentioned previously, double barreling was also a problem specifically in this study to questions 3J "... bathing and dressing" and 3F "...bending, kneeling or stooping."

Some participants could bend and kneel but not stoop, to which they chose 'limited a little,' due to confusion⁵⁸.

Another study n = 195 administered the SF-36 to elderly participants 65 years and older by face-to face interview and by self-administration. Among the limitations described in the studies mentioned above, the study identified that question 3g, h and i were problematic. These questions asked about limitations in walking more than 1 mile, half a mile and 100 yards respectively. It was noted participants who could walk 1 mile found the other two to be irrelevant which caused frustration⁵⁹.

It is clear from the development of the SF-36 that patients have had no role in the development of the items and therefore contributed to the some of the key limitations mentioned above⁵⁷.

2.4.3 ICF component analysis

There have been no studies linking the ICF components to the SF-36 for osteoarthritis.

2.5 Conclusions

It is evident from the literature review that there several limitations that affect the quality of the most widely used lower limb osteoarthritis PROMs. The patient's perspective on the aforementioned scores has shown that responders often do not understand the question or interpret it in a way that many answers can be given. Many responders have found ways to limit their disability by using coping mechanisms and thus responders do not know what answer to write down; the actual or adjusted score. Pain questions were notoriously difficult to answer. For example, respondents failed to distinguish pain from their hip from other comorbidities in the joint. There were also a lot of factors that affected the response given for example, use of analgesia. Questions should also be specific and not ask about numerous tasks in one item as this caused confusion. Items should also be rated by importance, giving less weight to aspects that are not relevant to the responder. Responders couldn't discern whether their functional

limitations were due to their OA or other co-morbidities. Some contain irrelevant questions and responses that could be identified with by respondents. Some respondent required help to interpret the questions.

Many respondents have multi-site osteoarthritis, which can cause problems when answering outcome measures that assess a single joint for example the OKS. Respondents often find it difficult to assess how much of their functional limitations are caused by each joint in isolation. All the previously mentioned factors result in an inaccurate representation of their health.

Existing scores also do not incorporate a holistic view to functional assessment and commonly only include reflective factors. It is important to include other aspects like environmental and lifestyle factors, which can be modifiable. This would allow care-givers to assess if a change in functional capacity is due to pathology, intervention or other factors; a feature which is not available on previous scores.

3.0 Methodology

3.1 Overview

The aim of this study is to develop a novel patient reported outcome measure that holistically measures lower limb joint function in osteoarthritis.

There are standard methodologies regarding PROM development⁶⁰. A study flowchart is included in 3.6. Outlined below is the structure for the initial development of the novel PROM. Due to time restrictions, further development could not take place and suggestions for this will be presented in the conclusions chapter.

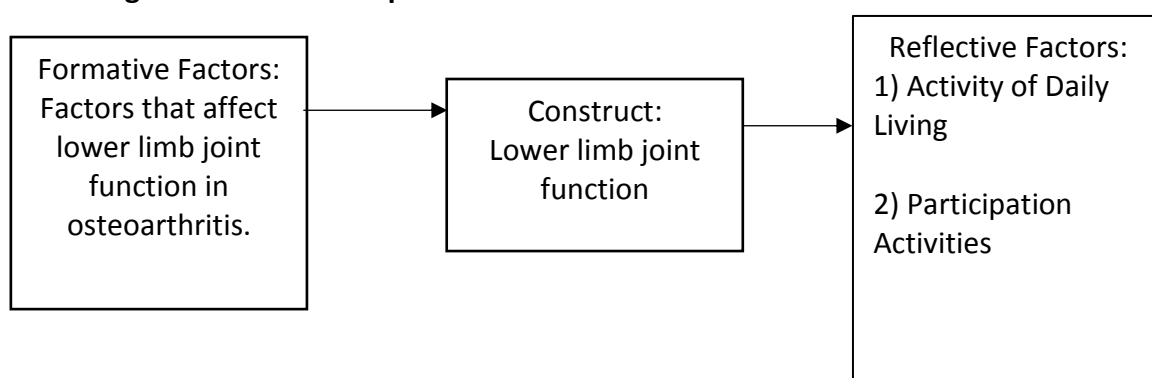
- 1) Define the construct.
- 2) Define the target population.
- 3) Define the purpose of the instrument.
- 4) Development of the items

Ethical approval for this study had been applied for and successfully approved on 28 July 2016 by the Health Research Authority.

3.2 Define the Construct

The construct will be the assessment of lower limb physical functional capacity in osteoarthritis. This multidimensional construct will involve both the ICF and formative/reflective models (Figure 3)

Figure 3 – Relationship between variables



3.3 Target Population

The methodology will allow the questionnaire to be used on patients whom are:

- Age 18+
- Male or female
- Have osteoarthritis of the hip and/or knee and/or the foot and/or the ankle.
- Patients whom have received secondary (hospital/outpatient) care.

3.4 Purpose of measurement

The instrument will be discriminative. It should allow the user to discriminate functional ability between people at a single point in time. The instrument will also be evaluative to assess responsiveness when there is clinical change due to pathology or to therapy³³.

3.5 Development

3.5.1 Item Generation

This stage will aim to obtain input from patient participants (patients) and expert participants (experts) as to the content of the PROM. A triangulation approach will be used using information from patient participants and expert participants to help identify concepts that will be used to generate items for the draft PROM. Triangulation is defined as the use of multiple methods to evaluate a single construct^{61, 62}. It is commonly used in qualitative research to strengthen the reliability and validity of the results. Use of one method would be inadequate as it provides an incomplete and under-representation of the construct. Data triangulation, specifically person, and methodological triangulation will be used in the development stage to provide diversity of information for the bases of item generation. Space triangulation would serve to enhance the generalisability of the research as more participants would be recruited from other areas of the UK. This is unavailable due to time and cost implications. The advantages of methodological triangulation is that the weaknesses of one method can be displaced by the advantages of another⁶². The disadvantages of this approach may lead to vast amount of information, which may not necessarily be a limitation,

considering a comprehensive set of formative factors is required⁶². However, with respect to questionnaire design, it can result in a high user burden as time taken to fill in the questionnaire can affect response rates especially in the elderly, which is common a demographic group in osteoarthritic patients⁶³. Despite limitations to triangulation, it will certainly add to the reliability and validity of the study⁶⁴.

Patients and experts were used to identify factors that affect lower limb function in osteoarthritis. This is because formative factors will characterise the breadth and definition of the construct and thus a comprehensive set of items is required. In contrast, reflective factors are manifestations of the construct and will not require a comprehensive set of items. Only patients were used, as experts would not have a better insight than the patient themselves.

3.5.1.1 Patient Participants

3.5.1.1.1 Recruitment and consent process for NHS patients

Patients were recruited from the outpatient department at The Royal Liverpool and Broadgreen University Hospitals. Patients were attending their routine appointments to see their orthopaedic surgeon, nurse practitioner or physiotherapists.

Patients were identified by asking their healthcare provider for their diagnosis. The patients had the study explained to them and if they were interested in the study, a patient information sheets was given (appendix F). To make this process free from coercion, patients were offered as much time as they required to read the information sheets. Should the patient want to request any more information, details were provided on the sheet and they could approach any member of staff in the department. If the patient decided to consent, their interview was arranged either on the day of their appointment or at a later date. A private consulting room within the department was allocated to this study. Consent forms are presented in appendix G

A review of the patient notes confirmed their diagnosis, site of their OA and reviewed for exclusion criteria. A Baseline Assessment included: age, sex, weight, height, site of OA, duration of symptoms, physical activity level, past medical history and current and past treatment for their OA (appendix H).

3.5.1.1.2 Sampling

The sampling method that used was purposeful⁶⁵. Purposive sampling is a method of ensuring particular cases are included in the study. Patients were recruited on various days of the week according to the relevant clinic: Monday knee participants, Wednesday hip participants and Thursday foot and ankle participants.

Inclusion criteria:

- 18+
- Diagnosis of osteoarthritis of the hip and/or knee and/or foot and/or ankle.

Exclusion criteria:

- Undiagnosed joint pain.
- Evidence of cognitive impairment

Patient participants were selected based on their medical history of lower limb osteoarthritis. Patients with undiagnosed joint pain were excluded. Patients with diagnosed cognitive deficits were excluded, as it would affect the recall of their disease perspective.

There is no literature on sample size calculation for qualitative PROM development. Thus, based on previous studies, a sample of 20 participants was initially used. The total sample size was decided when there was saturation of the data. Saturation was defined as point in data collection where no new information or themes emerge⁶⁶. After the initial data set from 20 participants has been collected, reiterations of 10 patients per round will ensue until saturation.

3.5.1.1.3 Data Collection

There are several methods for obtaining views in healthcare research. These are interviews, focus groups, observations and action research⁶⁷. Further distinction can be made to categorise interviews into structured, semi-structured and unstructured⁶⁶. Semi-structured interviews are generally based on a set of predetermined questions with other themes arising as a result of discourse. This is necessary as there are set questions to be asked based on conceptual frameworks. Structured interviews are not appropriate because the patient should be free to talk about their perspective on the disease, particularly the reflective factors. However, if information is not volunteered, probing for the categories on the ICF model was asked about. Similarly, unstructured techniques would not be appropriate as the entire patient experience is not required. For example, the quality of consultations in osteoarthritis clinics would be irrelevant to the construct.

The aims of focus groups are to facilitate discussion between participants and to share their experiences. There are various reasons why a group dynamic could be ineffective for obtaining information. There could be domination of the discussion and thus quieter participants may feel intimidated and less willing to divulge information, biasing the results. Research on conformity has shown that people do change their opinion due to the judgement of others^{68, 69}. This can occur due to group pressures that cause the individual to conform by fear of rejection/wanting to fit in (normative conformity) or (informational conformity) when members accepts a reduced level of expertise compared to the rest of the group and thus conform⁷⁰. Domination of the discussion can also be a problem.

It is crucial with patients that rapport and comfort are established during the interview process⁶⁷. This may influence how much patients are willing to share their experiences. Patients will be interviewed in a private room. Rapport will be built up using established techniques for example being respectful, non-judgmental and having open body language⁷¹. An interview guide will facilitate a standardised approach to each participant. This will involve the planning the

introduction and ending statements, considering how any adverse events will be dealt with and how to handle any sensitive topics that may come up. These have been documented in the ethical application.

Patients discourse was not audio or video recorded during the item generation stage. There are numerous articles on why interviews should be recorded, but a lack of information regarding the impact it has on the quality of the data. Audio and video recordings can modify their answers because it distorts their perception of their patient experience. This effect is produced because it can exacerbate any anxieties or fears the patient has^{72, 73}. In one study, interviews were not recorded and as a result, better outcomes were observed. Participants were relaxed and exchanged more information even if participants had consented to being recorded⁷². To mitigate this effect, information was noted down during the interview. Notes were not taken retrospectively as information can be forgotten, reducing the quality of the data set.

Semi- structured, individual, in depth, face-to-face interviews were used at this stage and the researcher was the interviewer^{74, 75}. The full interview guide is presented in the (appendix I).

Participants will be asked 2 questions:

- 1) Tell me about the effect the osteoarthritis has had on your life? (if information is not volunteered, probe for activity of daily living and participation restrictions).
- 2) What symptoms and/or other factors affect your ability to use your legs as you intend to (e.g. walking, standing up etc.)?

The formative indicators should comprehensively cover the entire aspect of the latent construct, therefore patients will be encouraged to think as holistically as possible⁷⁶. The endpoint of the interview will come when there is clear exhaustion

of ideas by the participant and no further questioning from the researcher. Information will be noted down on headed paper. Information on the notes will be repeated back to the patient to ensure validity. Patients who are non-English speakers will have a translator appointed to them. Back translation will also be done within the interview to ensure accuracy of translation⁷⁷.

3.5.1.1.4 Data Analysis

There are six main qualitative research models; 1) ethnography 2) phenomenology 3) grounded theory 4) discourse analysis 5) thematic analysis and 6) content analysis⁷⁸⁻⁸⁰.

- 1) Ethnography is the interpretation of cultures or groups of people, commonly analysing behavior, beliefs and language. This involves extended observation by the researcher to the population of study.
- 2) Phenomenological approach seeks “to understand the lived experience of individuals and their intentions within their life world.” It will provide a comprehensive understanding of human experience and meaning from the viewpoint of the participant. It relies on the assumption that what someone says has a good relationship to their “inner consciousness.”
- 3) Grounded Theory is a qualitative research method that uses an inductive approach to mitigate the limitations of any previous theory or models. New themes or theories will emerge as a result of analysis. Data collection occurs till no new concepts are emerging from the data set. These theories and hypotheses should be developed and tested, however most descriptions fall short of this process and commonly leads to good understanding of the lived experience.
- 4) Discourse analysis is the study of linguistics, commonly commenting on the cognitive processes in text comprehension and functional use of discourse.

5) Thematic analysis has been considered a part of the aforementioned theoretical frameworks. However, it is argued that thematic analysis is its own method and should be considered separately to those bound by the common qualitative philosophies. Thematic analysis can report reality and experiences of the participants or can examine these within a societal structure. It offers a more flexible approach to analysis which is unbound from theoretical perspectives^{78, 79}.

6) Content analysis looks at the content and contextual meaning of the text. There are three types of content analysis; conventional, directed or summative. Conventional content analysis generates codes during the analysis, so that there are no pre-conceived notions on the content of the data. Summative content analysis focuses on identifying codes and the frequency of each⁸⁰. Directed content analysis will be used in to analyses the data. This is because the ICF core set codes will be used to before data analysis and further coding will occur during analysis.

Each set of notes were read several times to familiarise the researcher with the dataset. Codes taken from the ICF core set were used initially to categorise data. Further codes were generated according to the data that were initially uncategorised.

3.5.1.2 Expert Participants

There are several ways to elicit the opinion of an expert or experts during qualitative research. Formal consensus methods have been developed to form robust methods of eliciting opinion and forming levels of agreement^{69, 81}. The three main techniques are 1) Delphi analysis 2) nominal group techniques and 3) The Consensus Development Conference Technique¹⁰⁵. For completeness, 4) Glaser's State-of-the-Art technique has been discussed as well^{69, 82, 83}. Unformal methods include unstructured discussion and focus groups⁸⁴.

- 1) Delphi method originated in 1948 and aimed to ascertain expert opinion⁸⁵. There are four fundamental characteristics to the Delphi technique: anonymity, iteration, controlled feedback and statistical group response⁸⁶. A 'Delphi' occurs when there is sufficient convergence of opinion or when there is a point where there is no more consensus can be reached despite repeated iterations⁸⁷. Experts are invited to form individual analyses from anonymised questionnaires which can be mailed via post or electronically. Although face-to-face interviews for round 1 have been recommended, due to improved response rates, the standard format of a questionnaire will be sent by e-mail⁸⁸. This is to ensure participants get ample time to think and reflect on the question. There are several reasons why e-mail will be used over postal mail. Firstly, information will be easily understood compared to handwriting which may be illegible. This results in easier data entry and interpretation and thus a reduced time between iterations. It would cost more to send questionnaires by mail and they risk being lost in the post⁸⁹. All participants will have access to e-mail being employees of RLBUHT.

After each round, results are collected and interpreted as to their level of consensus which is done statistically. The role of the researcher is to interpret the results of each iteration and co-ordinate the experts. Any exchange of information is done so in a very controlled manner. Experts should be defined before the start of any study and the definition justified. The number of rounds are flexible to obtain consensus, although usually this number is set to 3-4 iterations⁸¹. However, this is outside the remit of this thesis. Only round 1 was done.

Each expert can express their view without the coercion of others. Subject bias is reduced as participants are kept anonymised from each other. There are several pressures that occur due to being part of a group. It has been observed that participants can be pressured psychologically by having group members that have been perceived to have more expertise⁸⁷. This

can lead to inhibition and information can be withheld. Some respondents may openly agree but have deep reservations inside about the opinion they are agreeing to. This leads to 'early consensus'; no one disagrees, however no one completely approves⁹⁰. The anonymity provided by Delphi technique will benefit the quality of data obtained and validity of the study.

The Delphi technique importantly allows a well organised summary of the prior iteration. This will reduce the amount of error that can occur in a group environment. Participants can take their time in reviewing the iterations which benefits the process as it allows them to generate additional insights in a relaxed manner.

- 2) The Nominal Group Technique is another method to provide a structured communication process from experts within a technical area⁹¹. It gathers typically 8-10 experts in several rounds that last one session only. Each expert member will suggest content pertaining to the issue. These responses are collated, and a Likert-type scale is used to assess levels of agreement. The responses are re-distributed, and experts proceed to discuss reasons for non-consensus. The role of the leader here is to define the problem, decide when to proceed to the next step, co-ordinate the participants and decide when agreement has been reached. This rigorous approach demands a facilitator with significant expertise in the subject matter⁹¹. Consequentially, the benefits of the nominal group technique heavily relies on a well-trained leader and a group of 8-10 experts in a structured setting⁶⁹. This is a logistical issue as it will be difficult to plan and organise this type of session.
- 3) The Consensus Development Conference Technique was developed by the US National Institutes of Health⁶⁹. Their method has been modified over 100 times and is now used in other countries. The method differs because the expert panel involves using a public forum for discussion of issues. The technique spans numerous days and involves about 10 experts to reach

consensus. An open discussion occurs between experts who will be making decision within that particular area of research and the experts who will, to come to consensus. The ideal size of the decision-making panel is 6-12. Any type of evidence can be presented, and statements can be made openly, as compared to a questionnaire format like in the Delphi Analysis. A leader needs to be appointed and it is important they are independent and experienced. The interaction is not structured and a formal feedback system is not existent in the methodology.

- 4) Glaser's State-of the-Art Approach is an uncommon approach to structured communication. Similarly, to the nominal approach, it involves a small group of experts, however each member is allowed to choose additional members based on their recommendation of expertise. This creates two separate groups of experts, the 'core' group which is often selected by the investigator and the 'outside' group which is selected by the experts. This allows the core group to receive comments from the outside until there is consensus between the leader, core group and outside group. The leader remains principally the final editor. Similar to the nominal technique, the leader has to invest considerable time liaising with experts, however the leader does not need to be an expert, merely someone who is good at facilitating. The applicability to the field of psychology research methodology has not been evaluated yet, and has been applied to COPD research only⁸².

Overall, a Delphi analysis was chosen as it provides anonymous feedback which is controlled where ample time between rounds is given for the experts to think about the answers. This will be used for future research. Only round one of the Delphi analysis will be used in this study.

The definition of expert is ambiguous, it can be individuals who are going to be affected by the PROM and/or people with expertise in that area either with regard to knowledge or perceptions⁹². By definition, experts would include both patients

and healthcare professionals, however for ease participant groups have been called “patients” and “experts” (healthcare professionals). Expert participants should include professionals and should be heterogeneous⁸¹. Thus, orthopaedic surgeons and physiotherapists were recruited. A number of 15 would be satisfactory to include a heterogeneous sample of experts^{92, 93}. We have included those with substantial experience in lower limb orthopaedics.

3.5.1.2.1 Recruitment

Participants were recruited using posters displayed in the staff room of the orthopaedic outpatient department at RLBUHT (appendix J). Experts will be able to request an information sheet (appendix K) and consent form (appendix L) from contact details provided on the poster. A baseline assessment will consist of: Full job title (including grade if appropriate), year experience caring for patients with osteoarthritis of the hip and/or knee and/or foot and/or ankle, qualifications and regular use of outcome measures in their practice (appendix M).

3.5.1.2.2 Sampling

Purposive sampling will be used. The criteria to be used is as follows:

- 1) Is an orthopaedic surgeon, nurse or physiotherapist.
- 2) Has at least 5 years’ experience working with patients with osteoarthritis of the hip and/or knee and/or foot and/or ankle.

Sample size is ideally 15 participants. We will collect 18, in case there is any drop out.

3.5.1.2.3 Data Collection

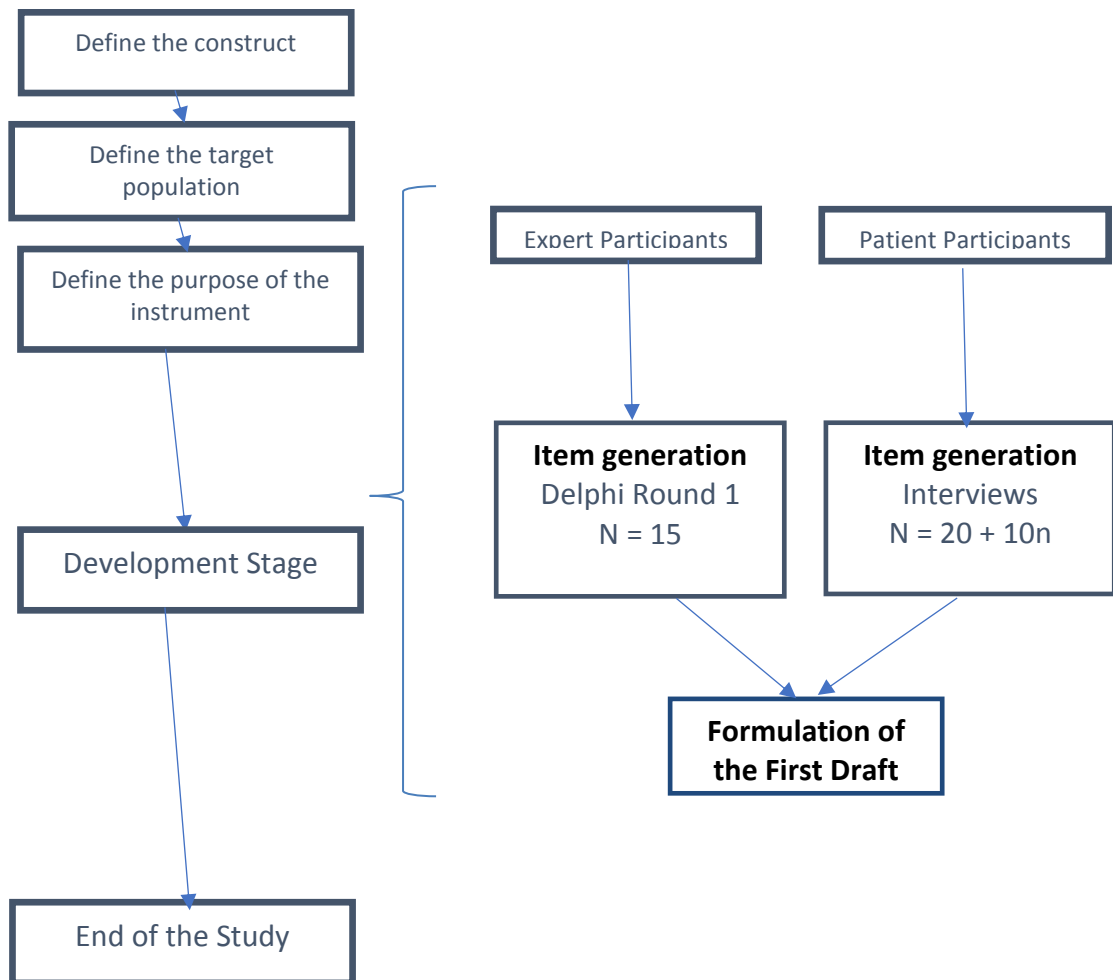
Round 1: Participants will be emailed questionnaires and asked to fill them in (appendix N). Participants will be asked to list the factors that can affect mobility in patients with osteoarthritis. They will be instructed to this as holistically as possible, however a guide will be included at the end for reference should the experts need to refer to it to generate ideas. Participants will be given a week to

display this information on the form and excluded if they have not replied despite repeated attempts to contact them. Further rounds will not be conducted as part of this thesis.

3.5.1.2.4 Data Analysis

Data will be analysed with directed content analysis⁸⁰. Codes taken from the ICF core set were used initially to categorise data. Further codes were generated according to the data that were initially uncategorised.

3.6 Study Flowchart



4.0 Results

4.1 Summary statistics

4.1.1 Patient Participants

20 patients were recruited for initial analysis. A further iteration of 10 patients was sufficient enough to achieve data saturation. Thus 30 patients were recruited in total. Table 3 shows summary statistics for patient participants. Table 4 shows distribution of OA at each joint. Table 5 shows co-morbidities present in the sample.

Summary statistic	Value
Mean Age (years)	67 (49-82 CI 95%)
Male: Female ratio	13:17
BMI (kg/m ²)	13-39 (mean = 30)
Mean duration of symptoms (years)	12
Mean duration of weekly physical activity (hours)	2

Table 3 – Summary statistics for patient participants

Distribution of OA	Number of patients
Bilateral hips	5
Left hip	2
Bilateral knees	4
Right knee	2
Bilateral ankle	1
Bilateral foot	2
Left foot	2
Left knee & left hip	1
Bilateral hips and knees	5
Bilateral foot and ankle, right knee and left hip	1
Bilateral hips and left knee	3
Bilateral ankle and knees	1
All lower limb joints	1

Table 4 – Distribution of OA for patient participants.

Patient participant co-morbidity	Number with condition
Atrial fibrillation	1
Hypertension	7
Angina	1
Unknown valvular heart disorder	1
Transient ischaemic attacks	1
Hypercholesterolaemia	3
Hypothyroidism	2
Bakers cyst	1
Hysterectomy	2
Cellulitis	1
Epilepsy	1
Dry eyes	1
Haemachromatosis	1
Depression	5
Malignant melanoma	2
Rheumatoid arthritis	1
Trigeminal neuralgia	1
Myocardial infarction	2
Gastroesophageal reflux disease	2
Plantar fasciitis	1
Asthma	1
Diverticulitis	1
Chronic fatigues syndrome/ polymyalgia rheumatic	3
Lung lobectomy (unknown diagnosis)	1
Appendicitis (has appendectomy)	1
Tuberculosis	1
Fibroids	2
Abdominal hernia	4
Polydactyly	1

Varicose veins	1
Malabsorption syndrome	1
Osteopenia	1
Anxiety	2
Shoulder surgery (unknown diagnosis)	1
Lumbar fracture	1
Mandible fracture	1
Hip fracture	1
Degenerative disc disease	1
Postural hypotension	1
Iron deficiency anaemia	1
Polycystic ovarian syndrome	1
Wrist fracture	1
Gastritis	1
Benign paroxysmal vertigo	1
Diabetes type 2	1
Tonsillitis	1

Table 5 – Co-morbidities present in sample

4.1.2 Expert Participants

18 experts were recruited for the study. 11 experts had replied and thus were used for analysis. A summary of their baseline information is presented in table 6.

Participant number	Job title?	How many years experience they had with patients with OA of the lower limb?	Qualifications	Did they regularly use outcome measure in their practice?
1	Extended support physiotherapist	31	MSc Advanced Practice	Yes
2	Chartered physiotherapist	20	BSc Physiotherapy	Yes
3	Consultant foot and ankle surgeon	25	MBBS, MCh, FRCS, FRCS (T+O)	Yes
4	Orthopaedic registrar	10	MBBS, MRCS, FRCS(T+O)	Yes
5	Extended service physiotherapist	25	GradDipPhys	Yes
6	Orthopaedic surgeon – Hip fellow	9	MBBS, MS(ORTH), DNB, MCh(ORTH), MRCS Ed, FRCS Ed(Tr&ORTH)	Yes
7	Research physiotherapist	24	BSc physio (hons), PhD	Yes
8	Consultant hip and knee surgeon	13	MBBS, MRCS, FRCSOrth	Yes
9	Orthopaedic surgeon, shoulder and elbow fellow	10	MBChB, BSc, MRCS, FRCS Ortho	Yes
10	Consultant Orthopaedic surgeon hip and knee	11	MBChB, MSc, MRCS, FRCS Ortho	Yes
11	Consultant orthopaedic surgeon hip and knee	13	MBChB, MRCS, FRCS Ortho	Yes

Table 6 – Summary statistics from expert participants

4.2 Results from content analysis

Raw data from patients can be found in appendix O. Raw data from experts can be found in appendix P.

4.2.1 Formative factors

Several codes deduced from the ICF core set were used. Find this data in appendix Q. However, there were several data points that could not be coded and thus addition codes were created.

ICF codes used were:

- 1) Products and technology for personal use in daily living
- 2) Products and technology for employment
- 3) Design, construction and building products and technology of buildings for public use
- 4) Climate
- 5) Immediate family
- 6) Personal care providers and personal assistants
- 7) Health professionals
- 8) Individual attitudes of immediate family members
- 9) Individual attitudes of health professionals
- 10) Transportation services, systems and policies
- 11) General social support services, systems and policies

Addition codes:

- 1) Symptoms of osteoarthritis (limp, pain, pain control, mechanical symptoms, stiffness, swelling and deformity)
- 2) Co-morbidities (pulmonary, psychiatric, cardiac, musculoskeletal, general and neurological.)
- 3) Individual attitudes/behaviors and coping strategies. (fear, motivation, other)

4.2.2 Reflective factors

Find raw data in the appendix R.

ICF codes used were:

- 1) Changing basic body position (kneeling down, moving into chair, moving onto the floor, moving out of bed, bending)
- 2) Maintaining a body position
- 3) Lifting and carrying objects
- 4) Fine hand use
- 5) Hand and arm use
- 6) Walking [general walking, circumstantial walking]
- 7) Moving around [stairs, others]
- 8) Using transportation [bus, car, taxi]
- 9) Washing oneself
- 10) Dressing [General, specific activities]
- 11) Doing housework
- 12) Assisting others
- 13) Intimate relationships
- 14) Recreation and leisure

All data points were satisfactorily coded into these and thus no new codes were created.

4.3 Results of Item Generation

4.3.1 Description of the conversion between data set to items.

The results of the patient interviews and first round of the Delphi analysis produced concepts that were converted into items. The process is described below. Edits were done according to the opinions of the author solely.

4.3.1.1 Formative factors

Symptoms of osteoarthritis: 'Local or generalised pain' was differentiated into leg pain and into general body pain to make it simpler to understand. 'Pain on ambulation' was perceived as too technical for the layman and as such ambulation

was changed to walking. The rest of the generated concepts were inputted into the PROM unmodified.

'Strength in legs' and 'weakness' were seen as negative statement of each other. Thus, weakness was omitted from the PROM and strength remained as most of the answers referred to 'strength' or 'muscle power.' 'Quadriceps strength' was deemed to be too specialised for the layman, and as such the concept was incorporated into, 'strength in the LL(lower limb) muscles individually.' 'Muscle tone' is a medical examination finding and thus was excluded from the PROM. 'Muscle co-ordination' was included unchanged.

'Limping' went directly into the PROM unchanged. 'Stability' of the joint was included as the use of 'instability' in creating a question would create a double-negative item. This could create confusion. Joint alignment would not be appropriate as this is a technical finding on examination and radiography, thus not suitable for self-report. In any case, this theme would be covered by the question on deformity. 'Locking, clicking' were added unmodified. Although not mentioned in the responses, an option for instability for the hip was added, as this can occur as part of osteoarthritis or a post-operative complication for total hip arthroplasty. 'Crepitus' was replaced with the word, 'grinding' as it is not usually part of the layman's lexicon. Most responses referred to stiffness of the lower limb as a whole. One has referred to the hip and knee specifically. Thus, stiffness of each joint was referred to in the PROM. One response referred to 'stiffness actual or perceived.' Actual stiffness cannot be measured by self-report and thus was omitted from the PROM.

The comorbidity items were modified as follows. 'Oxygen problems and lung capacity on account of my COPD' and 'Co-morbidities which affect exercise tolerance e.g. angina' can include a range of pulmonary and extra pulmonary symptoms that can affect joint function. Therefore, these were grouped together and referred to as 'lung problems.' 'Breathlessness' was kept unedited. 'Cardiac problems' was referred to as heart problems for simplification. Circulatory

problems have been added unchanged, with examples given in the text as users may find it hard to decipher central from peripheral vascular diseases. 'Mood,' 'depression' and 'mental health' were all collated into an item of 'mental health.' 'Backache,' 'back pain,' 'low back pain' were grouped together to 'back pain.' 'Range of movement in the joint above or below,' was changed to movement of the spine as there is no joint distal to the joints of the foot. 'Back pain and stiffness' are already incorporated in the previous answer and thus was not specially used in the PROM. Neck and hand OA were modified to say, 'osteoarthritis of joints other than your leg.' 'Absent or short leg' were used unmodified. 'Ruptured tendon' was modified to 'ligament/tendon breaks' for simplicity. Similarly, 'Previous trauma, number of previous surgeries to the leg; was modified to make it more suitable for the layman. 'Deformity (e.g. flat foot, malunion after fracture long bone- femur or tibia' was omitted as the question on deformity previously (as part of symptoms of osteoarthritis) would encompass this concept. 'Weight' and 'balance' were included unmodified. 'Proprioception' is a medical word and was changed to sense of joint position. It is anticipated users may be reluctant to answer these questions due to the ambiguity of the layman translation, however this should be tested in future study. 'Allergies' was included unchanged. 'Impaired neurological function' and 'Neurological conditions affecting muscle strength of co-ordination e.g. Parkinson's' were grouped together as they were deemed similar. 'Altered spatial awareness, position perception e.g. vision, hearing dementia, post CVA' was reworded to Altered awareness of position in space (due to neurological disease e.g. visual or hearing problems), which was perceived to be simpler to understand. 'Loss of sensation (foot numbness secondary to nerve injury or peripheral neuropathy' was reworded to make it simpler. 'Weakness of lower limb (e.g. after stroke or polio)' was included. 'Cognitive impairment affecting the understanding of need to exercise/move joints,' was not included as this was perceived to be offensive to the user.

The next theme involved products and technology for personal use in daily living. Responses included use of 'assistive devices like crutches and walking frames,' 'aids or braces' and 'walking aids.'. These were merged to 'assistive devices'.

'Access to home adaptations like shower, rails on stairs, stair lift' was used unmodified. The subtheme of footwear included responses of 'quality of shoes' 'difficulty with footwear' and 'inappropriate footwear.' The former two responses were merged into one item stating, 'quality of footwear' as it would encompass it. The next theme involved products and technology for employment. 'work equipment availability' was included with no modification. The theme of climate had one response with 'climate,' which was included unaltered. The theme of 'immediate family' had two responses of 'Relying on wife to do activities (assistance)' and 'family support.' This was merged to 'availability of assistance from family members' as it would potentially exclude people that have assistance from other members of their family.

The next theme regards health professional. 'Concordance between healthcare professional and individuals' was reworded to 'any disagreement between you and your healthcare provider over treatment.' 'Patients understanding of procedure and the post op protocol,' was deemed to be too specific for surgical management and does not incorporate medical management. Therefore, it was reworded to 'your understanding of the treatment and further care.' 'Radiographic severity of osteoarthritic disease, Implant positioning and Pre-op level of function and steps to correct e.g. posterior release in TKR' would not be appropriate to ask in a PROM as they are all medical factors and cannot be done by self-report. Individual attitudes of immediate family members include responses, 'beliefs of others (friends and family influences/societal influences.' This was included unedited.

Individual attitudes of health professionals had one response, 'attitude of healthcare professionals e.g. empathy, listening,' which was included unedited. Transportation services, systems and policies had one response with 'quality of public transportation – if the buses can lower themselves etc.,' which was similarly used unedited. There were two responses under the theme of 'personal care providers and assistants': 'Social services support e.g. shopper, cleaner' and 'other people helping him; cleaner.' The responses are similar and therefore was merged

into 'availability of personal care providers e.g. shoppers and cleaners.' Under health services, systems and policies four responses were given, 'Media influences e.g. websites,' 'physiotherapy access,' 'access to equipment to aid rehabilitation e.g. walking aids, gym or swimming pool' and 'patient experience during hospital stay.' All but 'walking aids' were omitted the item was generated under another theme. 'Hospital stay' was reworded to only include orthopaedic interventions. The next theme was included deductively: individual attitudes or behaviours and included. Subthemes include fear, motivation, coping strategies and others. Responses included, 'fear,' 'fear of an injury,' 'fear of falling,' fear and avoidance of moving due to pain,' 'trusting the joint to move as it intends to,' 'knowledge of whether moving the joint will make the joint worse,' 'Personal belief and expectations e.g. more ambulation = more harm,' 'confidence while using sticks' and 'people watching me walk is embarrassing.' There are several instances of different aspects of fear. Thus, items were generated to involve, fear of injury, fear of falling and fear of pain. The other responses were included unedited except the two related to fear of ambulation would lead to more harm which were merged as they were deemed similar. Responses under motivation included, 'my own effort to move around,' 'willingness to move about,' 'motivation to go for a walk' and 'motivation' were similar and thus grouped together as personal motivation. All coping strategies responses were merged into one item. Lastly, 'personality' was included unchanged.

4.3.1.2 Reflective factors

Formative responses remained largely unchanged except for a few items. 'Rolling off bed to get up' and 'getting out of bed' were similar responses and were merged to form 'getting out of bed'. All the bending down responses were changed to a single 'bending down' item given with examples noted from the responses of 'pick something up or put on socks.' Walking had responses that included, 'walking,' 'walking <100yards' and 'walking generally.' These were merged to form the item of 'walking.' The stairs subtheme had responses of both 'climbing stairs,' 'descending stairs' and both 'getting up and getting downstairs. To avoid enquiring about many tasks in one question they were separated into individual tasks.

Similarly, for 'getting in and out of a car...bus...taxi,' 'getting in and out of a bath,' 'getting in and out of a shower' and 'putting on socks and shoes,' was separated into its individual components. Under the theme of assisting others responses included, 'looking after my wife who's a wheelchair user' and 'looking after my grandson.' These were merged and examples given based on the responses. There were various responses under the theme of recreation and leisure. These formed 4 items that were deemed to be independent of each other and encompass all of the responses: 'sports,' 'shopping,' 'social activities like gardening,' 'other leisurely activities (e.g. walking the dog).'

4.3.2 Items

The results of item generation:

Formative factors:

1) Symptoms of osteoarthritis

a) Pain

- I. How much does the joint pain in your legs stop you from mobilising as you intend to?
 - i. With painkillers
 - ii. Without painkillers
- II. How much does the joint pain in your legs while at rest stop you from mobilising as you intend to?
 - i. With painkillers
 - ii. Without painkillers
- III. How much does the joint pain in your legs while walking stop you from mobilising as you intend to?
 - i. With painkillers
 - ii. Without painkillers
- IV. How much does your general body pain stop you from mobilising as you intend to?
 - i. With painkillers
 - ii. Without painkillers

b) Stiffness

- I. How much does the stiffness in your hips stop you from mobilising as you intend to?
- II. How much does the stiffness in your knees stop you from mobilising as you intend to?
- III. How much does the stiffness in the foot and ankle stop you from mobilising as you intend to?

c) Swelling

- I. How much does the joint swelling in your legs stop you from mobilising as you intend to?

d) Deformity

- I. How much does your leg deformity stop you from mobilising as you intend to?
- II. How much does the difference in your leg lengths stop you from mobilising as you intend to?
- III. How much does your limp stop you from mobilising as you intend to?

e) Mechanical symptoms

- I. How much does the instability in your foot or ankle stop you from mobilising as you intend to?
- II. How much does the instability in your knees stop you from mobilising as you intend to?
- III. How much does the instability of your hips stop you from mobilising as you intend to?
- IV. How much does the locking of your leg stop you from mobilizing as you intend to?
- V. How much does the clicking/grinding of your leg stop you from mobilizing as you intend to?

2) Co-morbidities

a) Pulmonary

- I. How much does your breathlessness stop you from mobilising as you intend to?
- II. How much do your lung problems stop you from mobilising as you intend to?

b) Cardiac

- I. How much do your heart problems stop you from mobilising as you intend to?
- II. How much do your circulation problems (e.g diseases affecting your blood vessels like peripheral vascular disease) stop you from mobilising as you intend to?

c) Musculoskeletal

- I. How much does your back pain stop you from mobilising as you intend to?
- II. How much does loss of movement at the spine stop you from mobilising as you intend to?
- III. How much does your osteoarthritis of other joints than in the leg stop you from mobilising as you intend to?
- IV. How much does any previous or current ligament/tendon breaks stop you from mobilising as you intend to?
- V. How much do your previous leg surgeries stop you from mobilising as you intend to?
- VI. How much does any previous injury to your leg stop you from mobilising as you intend to?
- VII. How much does the strength of your hip muscles stop you from mobilising as you intend to?
- VIII. How much does the strength of your knee muscles stop you from mobilising as you intend to?
- IX. How much does the strength of the leg muscles as a whole stop you from mobilising as you intend to?
- X. How much does your muscle co-ordination problems stop you from mobilising as you intend to?

d) Neurological

- I. How much do any problems that affect balance stop you from mobilising as you intend to?
- II. How much do any problems that affect your ability to sense your joint position in space stop you from mobilising as you intend to?
- III. How much does your neurological disease affect your ability to mobilise as you intend to?
- IV. How much does your altered awareness of position in space (e.g. hearing problems, vision problems, stroke etc.) stop you from mobilising as you intend to?
- V. How much does your loss of sensation in the legs stop you from mobilising as you intend to?
- VI. How much does your weakness in the legs stop you from mobilising as you intend to?

e) Psychiatric

- I. How much do your mental health problems stop you from mobilising as you intend to?

f) General health issues

- I. How much does your weight stop you from mobilising as you intend to?
- II. How much does your levels of tiredness stop you from mobilising as you intend to?
- III. How much do your allergies stop you from mobilising as you intend to?

3) Products and technology for personal use in daily living

a) Walking aids

- I. How much does any assistive devices (e.g. walking aids) help you to mobilise as you intend to?

b) Home modifications

- I. How much do your home modifications (e.g. stair lift or extra railings) help you to mobilise as you intend to?

- c) Footwear
 - I. How much does your footwear (quality or appropriateness) stop you to mobilise as you intend to?
- 4) Products and technology for employment
 - a. How much does any equipment at work (e.g. foot rest) help you to mobilise as you intend to?
- 5) Climate
 - a. How much does the weather stop you mobilising as you intend to?
- 6) Personal care providers
 - a. How much do any personal care providers e.g. shoppers or cleaners help you mobilise as you intend to?
- 7) Immediate family
 - a. How much does the availability of assistance from family members help you to mobilise as you intend to?
- 8) Health professionals
 - a. How much do any disagreements between you and your healthcare providers stop you from mobilising as you intend to?
 - b. How much does your lack of understanding of treatment and further care of your osteoarthritis stop you from mobilising as you intend to?
- 9) Individual attitudes of immediate family members
 - a. How much do the beliefs of others stop you from mobilising as you intend to?
- 10) Individual attitudes of health professionals
 - a. How much do the attitudes of your healthcare professionals (e.g. being caring or listening) stop you from mobilising as you intend to?
- 11) Transportation services, systems and policies
 - a. How much does the quality of public transportations services affect your ability to mobilise as you intend to?
- 12) General social support services, systems and policies
 - a. How much do media influences (e.g. websites) affect your ability to mobilise as you intend to?

- b. How much does your access to physiotherapy affect your ability to mobilise as you intend to?
- c. How much does your access to rehabilitation services (e.g. gyms or swimming pools) affect your ability to mobilise as you intend to?
- d. How much does your experience during your hospital stay (during an orthopaedic admission) affect your ability to mobilise as you intend to?

13) Health services systems and policies

- a. How much does the availability of rehabilitation equipment (e.g. use of gyms, walking aids, swimming pools) help you to mobilise as you intend to?

14) Individual attitudes/behaviors

- a. How much does your fear of falling stop you from mobilising as you intend to?
- b. How much does your fear of pain stop you from mobilising as you intend to?
- c. How much does your fear of injury stop you from mobilising as you intend to?
- d. How much does your trust of your joint moving as it intends to affect your ability to mobilise and you intend to?
- e. How much does your knowledge of 'moving the joint will make the joint worse' affect your ability to mobilise as you intend to?
- f. How much does your confidence while using sticks affect your ability to mobilise as you intend to?
- g. How much does any embarrassment caused by other people watching you walk affect your ability to mobilise as you intend to?
- h. How much does your personal motivation affect your ability to mobilise as you intend to?
- i. How much does your personality affect your ability to mobilise as you intend to?

15) Coping strategies

- a. How much do your coping strategies (e.g. walking upstairs backwards or use of a vehicle that is higher) affect your ability to mobilise as you intend to?

Reflective factors

1) Changing basic body position

- a. How much difficulty have you had kneeling down?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- b. How much difficulty have you had sitting down in a chair?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- c. How much difficulty have you had standing up from a chair?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- d. How much difficulty have you had sitting on a floor?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- e. How much difficulty have you had standing up from the floor?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- f. How much difficulty have you had getting out of bed?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- g. How much difficulty have you had bending down(e.g. to pick something up or put on socks)?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

2) Maintaining a body position

- a. How much difficulty do you have in standing idle for a period of time?
 - i. With assistive device or coping strategy?

- ii. Without assistive device or coping strategy?
- 3) Lifting and carrying objects
 - a. How much difficulty do you have in carrying objects in the hand (e.g. bags)?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
 - b. How much difficulty do you have in holding objects in both hands (e.g. a walking stick and umbrella)?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- 4) Fine hand use
 - a. How much difficulty do you have in cutting vegetables?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
 - b. How much difficulty do you have in cutting toenails?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- 5) Hand and arm use
 - a. How much difficulty do you have in pushing a trolley?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- 6) Walking
 - a. How much difficulty do you have generally walking?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
 - b. How much difficulty do you have walking home?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
 - c. How much difficulty do you have walking to work?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
 - d. How much difficulty do you have walking up a steep hill?

- i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- e. How much difficulty do you have walking on trails and rough woods?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- f. How much difficulty do you have walking on cobbled surfaces?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- g. How much difficulty do you have walking for long periods of time?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

7) Moving around

- a. How much difficulty do you have going upstairs?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- b. How much difficulty do you have going downstairs?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

8) Using transportation

- a. How much difficulty do you have getting in a car?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- b. How much difficulty do you have getting out of a car?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- c. How much difficulty do you have getting in a bus?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- d. How much difficulty do you have getting out of a bus?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

- e. How much difficulty do you have getting in a taxi?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- f. How much difficulty do you have getting out of a taxi?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

9) Washing oneself

- a. How much difficulty do you have washing yourself?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- b. How much difficulty do you have getting in a bath?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- c. How much difficulty do you have getting out of a bath?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- d. How much difficulty do you have getting in a shower?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- e. How much difficulty do you have getting out of a shower?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

10) Dressing

- a. How much difficulty do you have getting dressed?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- b. How much difficulty do you have in getting undressed?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- c. How much difficulty do you have on putting on socks?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

- d. How much difficulty do you have putting on shoes?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- e. How much difficulty do you have in putting on other footwear?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

11) Doing housework

- a. How much difficulty do you have in doing the dishes?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- b. How much difficulty do you have in hovering up?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- c. How much difficulty do you have in doing other housework?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

12) Assisting others

- a. How much difficulty do you have in assisting others e.g. grandchildren or others with special needs?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

13) Intimate relationships

- a. How much difficulty do you have with sexual activities?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

14) Recreation and leisure

- a. How much difficulty do you have with sports?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- b. How much difficulty do you have with shopping?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

- c. How much difficulty do you have with social activities like gardening?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?
- d. How much difficulty do you have other leisurely activities (e.g. walking the dog)?
 - i. With assistive device or coping strategy?
 - ii. Without assistive device or coping strategy?

5.0 Discussion

The aim of this thesis was to begin the process of developing a novel PROM to assess lower limb joint function. There were several important limitations of currently used PROMs that prompted the development of a novel one. Findings of this study provided an important quality source of information to describe the patients' and experts' opinion of how to assess of lower limb joint function. Semi structured interviews allowed the investigation of the patient experience and the first round of a Delphi analysis allowed for data collection from expert participants.

Content analysis has shown that there is a vast number of factors that contribute to lower limb joint function. The importance of this considering the clinical applicability of the scores, is that a change in score for a PROM that does not account holistically for factors that affect lower limb joint function will not prove whether the change in construct was due to disease/treatment or due to other factors. The codes for reflective factors were very similar to previous PROMs in use and content did not add significantly to these items. They also fit into the ICF coding system, which suggests there aren't any additional activity or participation restrictions that should be noted. It was useful to establish what activities were common in the population and thus should be specifically asked for in the novel PROM. Multivariate regression analysis could be used to identify how much any factor is affecting a person's lower limb joint function.

It was found from the literature search that there was a need for a PROM that addresses all the lower limb joints as one kinetic chain, as respondents found it hard to discern how much of their ability to walk was caused by a certain osteoarthritic joint or another. The bank of questions created here, asks about certain joints and the whole lower limb, as created by patients and experts. To allow for better content within the PROM, the items were created using patients who had osteoarthritis having had treatment ranging from simple pain killers to total joint replacements. Previous PROMs have not been created by using

patients having undergone replacement surgeries, and thus the use of them in clinical practice after joint replacement is not appropriate. The sample used in this study includes various participants who have undergone a variety of treatments varying from painkillers, to total joint replacement surgery. To address the problem of using a coping mechanism or assistive devices, it was deemed necessary to split up each reflective question into two, so that respondents can answer it in both fashions, to get a true state of their disability for times when they can't use their coping mechanism or assistive device. Respondents using the current PROMs found it difficult to distinguish how much of their pain came from joint problems or other comorbidities in the region, unfortunately, this could not be solved within the item generation stage and would be useful to specifically interview during the qualitative pilot stage of future research. We did not use double or triple barreled questions, as seen in previous PROMs. Some respondents suggested that items were irrelevant and thus importance should be given to these. There are various ways that weighting can be given to items in PROMs, however it goes outside the remit of this thesis and should be discussed in future research. We have partially solved the issue of pain, by asking levels of pain, with and without pain killers.

Although this is a good start, it is difficult at this stage of the research to provide conclusive evidence of the extent to which previous qualitative issues have been resolved. It is only when the pilot testing occurs and any further study of patient perspectives is done, can good evidence be produced. Nevertheless, within this study, items have been designed to try and allow for a more accurate response to be inputted by a respondent.

The use of mixed methods has been one of the primary strengths of this study, in addition to the recruitment of patients with a variety of ages, BMI, treatments of their OA, and various single and multi-sites of their OA/ recruitment of experts with varying levels of expertise at different training levels.

There are several limitations to this study. Firstly, is to discuss whether the questions asked adequately reflect the construct we are trying to measure? Although, we have based it on the ICF model, it would be important to ask experts in a separate study, the extent to which it does as part of a face and content validity study. Secondly, the baseline characteristics of the patient participants may not match those of the general public i.e. do these participants match the typical sample that would be coming in to secondary orthopedic clinics in the whole of the UK. It could have been said, that due to the fact formative factors define the construct a literature search should have been performed to obtain the absolute maximum data. This step was a limitation, and was omitted, because it was felt that the answers should come directly using patients and experts.

6.0 Conclusions

This study has generated novel and potentially important contributions to the field of orthopaedic surgery. It has created a bank of items that holistically assess lower limb joint function using osteoarthritis as the model. This has formed the initial stage of developing a PROM. Future research should aim to continue the development and validation process to create a final version that is suitable for clinical practice. This was impractical, due to the time constraints of the study.

Further research should:

- Reduce the number of items, continuing with the Delphi analysis.
- Pilot the PROM qualitatively and quantitatively
- Validate the PROM.

It would be useful in future study to link concepts created in this study to the ICF classification. This information can be presented to the ICF to show that other variables (than shown in their own set) can impact on the QoL of patients with osteoarthritis. This will aid researchers understanding of the impact factors have on joint function. The data produced in this study could also be used to educate healthcare staff and students about assessment of lower limb joint function and the typical difficulties that are associated with having osteoarthritis in the lower limb joints.

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8.0 Appendix

A – Comprehensive ICT Core Set for Osteoarthritis

Comprehensive ICF Core Set for Osteoarthritis

Categories of the component 'body functions':

ICF Code	ICF Category Title
2 nd Level	
b130	Energy and drive functions
b134	Sleep functions
b152	Emotional functions
b280	Sensation of pain
b710	Mobility of joint functions
b715	Stability of joint functions
b720	Mobility of bone functions
b730	Muscle power functions
b735	Muscle tone functions
b740	Muscle endurance functions
b760	Control of voluntary movement functions
b770	Gait pattern functions
b780	Sensations related to muscles and movement functions

Categories of the component 'body structures':

ICF Code	ICF Category Title
s720	Structure of shoulder region
s730	Structure of upper extremity
s740	Structure of pelvic region
s750	Structure of lower extremity
s770	Additional musculoskeletal structures related to movement
s799	Structures related to movement, unspecified

Categories in **bold** belong to the Brief ICF Core Set for Osteoarthritis.

Comprehensive ICF Core Set for Osteoarthritis

Categories of the component '*activities and participation*':

ICF Code	ICF Category Title
d410	Changing basic body position
d415	Maintaining a body position
d430	Lifting and carrying objects
d440	Fine hand use
d445	Hand and arm use
d450	Walking
d455	Moving around
d470	Using transportation
d475	Driving
d510	Washing oneself
d530	Toileting
d540	Dressing
d620	Acquisition of goods and services
d640	Doing housework
d660	Assisting others
d770	Intimate relationships
d850	Remunerative employment
d910	Community Life
d920	Recreation and leisure

Categories in **bold** belong to the Brief ICF Core Set for Osteoarthritis.

Comprehensive ICF Core Set for Osteoarthritis

Categories of the component '*environmental factors*':

ICF Code	ICF Category Title
2 nd Level	
e110	Products or substances for personal consumption
e115	Products and technology for personal use in daily living
e120	Products and technology for personal indoor and outdoor mobility and transportation
e135	Products and technology for employment
e150	Design, construction and building products and technology of buildings for public use
e155	Design, construction and building products and technology of buildings for private use
e225	Climate
e310	Immediate family
e320	Friends
e340	Personal care providers and personal assistants
e355	Health professionals
e410	Individual attitudes of immediate family members
e450	Individual attitudes of health professionals
e460	Societal attitudes
e540	Transportation services, systems and policies
e575	General social support services, systems and policies
e580	Health services, systems and policies

Categories in **bold** belong to the Brief ICF Core Set for Osteoarthritis.

Appendix B – Oxford Hip Score

OXFORD HIP SCORE QUESTIONNAIRE

Please answer the following 12 questions. Choose only one answer per question. The value for each answer is indicated to the right of the answer. Total up all of your answers to obtain a total score out of 48 points. Please only consider how you have been getting on during the past four weeks| Side: R / L

1. How would you describe the pain you usually have in your hip?	Score	7. Have you been able to put on a pair of socks, stockings or tights?	Score
None – 4		Yes, easily – 4	
Very mild – 3		With little difficulty – 3	
Mild – 2		With moderate difficulty – 2	
Mild/moderate – 1		With extreme difficulty – 1	
Severe – 0		No, impossible – 0	
2. Have you been troubled by pain from your hip in bed at night?		8. After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your hip?	
No nights – 4		Not at all painful – 4	
Only 1 or 2 nights – 3		Slightly painful – 3	
Some nights – 2		Moderately painful – 2	
Most nights – 1		Very painful – 1	
Every night – 0		Unbearable – 0	
3. Have you had any sudden, severe pain-'shooting', 'stabbing', or 'spasms' from your affected hip?		9. Have you had any trouble getting in and out of a car or using public transportation because of your hip?	
Rarely/never – 4		No trouble at all – 4	
Sometimes or just at first – 3		Very little trouble – 3	
Often, not just at first – 2		Moderate trouble – 2	
Most of the time – 1		Extreme difficulty – 1	
All of the time – 0		Impossible to do – 0	
4. Have you been limping when walking because of your hip?		10. Have you had any trouble with washing and drying yourself (all over) because of your hip?	
Yes, easily – 4		No trouble at all – 4	
With little difficulty – 3		Very little trouble – 3	
With moderate difficulty – 2		Moderate trouble – 2	
With extreme difficulty – 1		Extreme difficulty – 1	
No, impossible – 0		Impossible to do – 0	
5. For how long have you been able to walk before the pain in your hip becomes severe (with or without a walking aid)?		11. Could you do the household shopping on your own?	
No pain for 30 minutes or more – 4		Yes, easily – 4	
16 to 30 minutes – 3		With little difficulty – 3	
5 to 15 minutes – 2		With moderate difficulty – 2	
Around the house only – 1		With extreme difficulty – 1	
Not at all – 0		No, impossible – 0	
6. Have you been able to climb a flight of stairs?		12. How much has pain from your hip interfered with your usual work, including housework?	
Yes, easily – 4		Not at all – 4	
With little difficulty – 3		A little bit – 3	
With moderate difficulty – 2		Moderately – 2	
With extreme difficulty – 1		Greatly – 1	
No, impossible – 0		Totally – 0	

Total Score: /48

Appendix C – Oxford Knee Score

Item	Scoring categories
<i>During the past four weeks</i>	
1) How would you describe the pain you usually have from your knee?	1 None 2 Very mild 3 Mild 4 Moderate 5 Severe
2) Have you had any trouble with washing and drying yourself (all over) because of your knee?	1 No trouble at all 2 Very little trouble 3 Moderate trouble 4 Extreme difficulty 5 Impossible to do
3) Have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you tend to use)	1 No trouble at all 2 Very little trouble 3 Moderate trouble 4 Extreme difficulty 5 Impossible to do
4) For how long have you been able to walk before the pain from your knee becomes severe? (with or without a stick)	1 No pain/>30 min 2 16 to 30 min 3 5 to 15 min 4 Around the house only 5 Not at all - severe on walking
5) After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?	1 Not at all painful 2 Slightly painful 3 Moderately painful 4 Very painful 5 Unbearable
6) Have you been limping when walking, because of your knee?	1 Rarely/never 2 Sometimes or just at first 3 Often, not just at first 4 Most of the time 5 All of the time
7) Could you kneel down and get up again afterwards?	1 Yes, easily 2 With little difficulty 3 With moderate difficulty 4 With extreme difficulty 5 No, impossible
8) Have you been troubled by pain from your knee in bed at night?	1 No nights 2 Only 1 or 2 nights 3 Some nights 4 Most nights 5 Every night
9) How much has pain from your knee interfered with your usual work (including housework)?	1 Not at all 2 A little bit 3 Moderately 4 Greatly 5 Totally
10) Have you felt that your knee might suddenly "give way" or let you down?	1 Rarely/never 2 Sometimes or just at first 3 Often, not just at first 4 Most of the time 5 All of the time
11) Could you do the household shopping on your own?	1 Yes, easily 2 With little difficulty 3 With moderate difficulty 4 With extreme difficulty 5 No, impossible
12) Could you walk down a flight of stairs?	1 Yes, easily 2 With little difficulty 3 With moderate difficulty 4 With extreme difficulty 5 No, impossible

Appendix D – Western Ontario McMaster Universities Index

Instructions: Please rate the activities in each category according to the following scale of difficulty: 0 = None, 1 = Slight, 2 = Moderate, 3 = Very, 4 = Extremely

Circle **one number** for each activity

Pain	1. Walking	0	1	2	3	4
	2. Stair Climbing	0	1	2	3	4
	3. Nocturnal	0	1	2	3	4
	4. Rest	0	1	2	3	4
	5. Weight bearing	0	1	2	3	4
Stiffness	1. Morning stiffness	0	1	2	3	4
	2. Stiffness occurring later in the day	0	1	2	3	4
Physical Function	1. Descending stairs	0	1	2	3	4
	2. Ascending stairs	0	1	2	3	4
	3. Rising from sitting	0	1	2	3	4
	4. Standing	0	1	2	3	4
	5. Bending to floor	0	1	2	3	4
	6. Walking on flat surface	0	1	2	3	4
	7. Getting in / out of car	0	1	2	3	4
	8. Going shopping	0	1	2	3	4
	9. Putting on socks	0	1	2	3	4
	10. Lying in bed	0	1	2	3	4
	11. Taking off socks	0	1	2	3	4
	12. Rising from bed	0	1	2	3	4
	13. Getting in/out of bath	0	1	2	3	4
	14. Sitting	0	1	2	3	4
	15. Getting on/off toilet	0	1	2	3	4
	16. Heavy domestic duties	0	1	2	3	4
	17. Light domestic duties	0	1	2	3	4

Total Score: _____ / 96 = _____%

Comments / Interpretation (to be completed by therapist only):

Appendix E – Short Form 36

SF-36 Questionnaire

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

1. In general, would you say your health is: (Circle One)	1. Excellent 2. Very Good 3. Good 4. Fair 5. Poor
---	---

2. Compared to one year ago, how would you rate your health in general at this time? (Circle One)	1. Much better now than one year ago 2. Somewhat better now than one year ago 3. About the same as one year ago 4. Somewhat worse than one year ago 5. Much worse now than one year ago
---	---

3. The following items are about activities you might do during a typical day. Does your health now <u>limit you</u> in these activities? If so, how much? (Circle the appropriate number for each question)

Activities	Yes, limited a lot	Yes, limited a little	No, not limited
a. Vigorous activities, such as running, lifting heavy Objects, or participation in strenuous sports	1	2	3
b. Moderate activities, such as moving a table, Vacuuming, bowling or golfing	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3

g. Walking more than a mile	1	2	3
h. Walking several blocks	1	2	3
i. Walking one block	1	2	3
j. Bathing or dressing yourself	1	2	3
4. During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of your physical health? (Circle the appropriate number for each question)			
a. Cut down on the amount of time you spent on work or other activities	Yes = 1	No = 2	
b. Accomplished less than you would like	Yes = 1	No = 2	
c. Were limited in the kind of work or other activities	Yes = 1	No = 2	
d. Had difficulty performing the work or other activities (For example – requiring an extra effort)	Yes = 1	No = 2	

5. During the past four weeks, have you had any of the following problems with your work or other regular daily activities as result of <u>any</u> <u>emotional</u> problems (such as feeling depressed or anxious)? (Circle the appropriate number for each question)		
a. Cut down on the amount of time you spent on work or other activities	Yes = 1	No = 2
b. Accomplished less than you would like	Yes = 1	No = 2
c. Didn't do work or other activities as carefully as usual	Yes = 1	No = 2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups? (Circle one)	1. Not at all 2. Slightly 3. Moderately 4. Quite a bit 5. Extremely
--	---

7. How much bodily pain have you had during the past 4 weeks? (Circle one)	1. None 2. Very mild 3. Mild 4. Moderate 5. Severe 6. Very severe
--	--

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one)	1. Not at all 2. Slightly 3. Moderately 4. Quite a bit 5. Extremely
--	---

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks: (Circle one number on each line)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc.)?(Circle one)	1. All of the time 2. Most of the time 3. Some of the time 4. A little of the time 5. None of the time
--	--

11. How TRUE or FALSE is each of the following statements to you?(Circle one for each line).					
	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

Appendix F – Patient participant information Sheet

Please turn over.

PATIENT PARTICIPANTS
INFORMATION
SHEET 1:
ITEM GENERATION

**Study Title: Development and Validation of a Patient
Reported Outcome Measure Assessing Lower Limb Joint
Function**

Contact information:

**Mr Joseph Alsousou (Principal
investigator)**

T: 0151 706 4120

E: josephalsousou@doctors.org.uk

Trupesh Patel (Research Student)

T: 0151 706 4688

E: t.patel@liv.ac.uk

**Ms Amanda Wood (Clinical
Research Nurse)**

T: 0151 706 4688

E: Amanda.wood@liverpool.ac.uk

Address:

Mr Alsousou or Trupesh Patel or
Amanda Wood,
Department of Molecular and Clinical
Cancer Medicine,
Royal Liverpool University Hospital,
Liverpool,
L69 3GA.

We would like to invite you to take part in a research study. Before you decide whether to take part, you need to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. This should take about 5 minutes of your time. If you have any questions do not hesitate to contact anyone listed at the end of this sheet.

Study Title

Development and validation of a patient reported outcome measure assessing lower limb joint function.

What is the purpose of this study?

Questionnaires or outcome measures are tools used to assess quality of life. They can be made up of different aspects such as pain, sleep function and mobility. These questionnaires are used to try and understand a patients' level of health at a certain point in time. They may also be used at different times to assess any potential changes in health due to treatment or progression of disease. Currently, several questionnaires are being used to assess mobility in patients with osteoarthritis of the hip, knee, foot or ankle. You may have already filled in similar questionnaires before. Although these are the best available, they do come with problems, for example some people may find the questions irrelevant, too difficult to understand or may take too much of their time! This study aims to develop a new questionnaire that resolves some of these problems. We are inviting patients with osteoarthritis of the hip, knee, ankle or foot. The study will be performed at the Royal and Broadgreen University Hospital Trust. This study will take part in many stages but you are being invited to one of them. Please continue reading to find out more details.

Why have I been chosen?

You have been selected because you have osteoarthritis of the hip, knee, foot or ankle joints.

What would taking part involve?

We would like to take the opportunity to inform you about the study. The study is divided into several stages that aim to create a new questionnaire. You are being invited to one of these stages. The aim of this stage is to develop questions that may potentially be used in the questionnaire. If you agree to take part in this study you will be given a consent sheet to sign and return. You will be asked to attend the orthopaedic clinic at Broadgreen Hospital, where a suitable time will be organized with you. Some personal information will be noted which will include your age, gender, weight, height, duration of symptoms, physical activity levels, medical history, current and past treatments of your osteoarthritis. We will also need to confirm your diagnosis of osteoarthritis by looking at your clinical notes. This research will involve you having an up to 30 minute interview with one member of the research team. They will ask you to comment on any problems that you face as a result of your osteoarthritis. For example walking, sitting down and getting in and out of a car etc. The researcher will also ask you to comment on anything that you feel affects your ability to move. For example pain, stiff joints, fear of an injury etc. The information you provide will be noted down on paper and will help us to create the new questions. This information will be securely stored and anonymized so that your personal details will NOT have any identifying information on it. After the interview has ended, you will no longer be part of the study. However, if you are interested in participating in other parts of this research please inform the research team.

What are the advantages and disadvantages of taking part?

There is no direct benefit to participating in this research. Your data will remain anonymized for the entirety of the study. We do not anticipate any risks or harm towards you during our study.

What if something goes wrong?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. The principal investigator Joseph Alsousou can also be contacted on 0151 706 4120, clinical research nurse Amanda Wood on 0151 706 4688 or Trupesh Patel 0151 706 4688.

What will happen if I don't want to carry on with the study?

Your decision to take part in this study is entirely voluntary; you can change your mind at any time. Any decision to take part, reject or withdraw from the study will NOT affect the NHS care you receive. Should you wish to withdraw from the study, a member of the research team can be approached. Your intentions regarding any information collected will be ascertained for example destroying the information.

Will my information be kept confidential?

All information that is collected will be kept strictly confidential. Information collected from you will be anonymised and stored in secure storage. Identifiable information will be stored separately to the information you provide as part of the study. Storage is located at the University of Liverpool.

What will happen to my information after the study?

At the end of the study we will, with your consent, submit an anonymised data set containing your information to the University of Liverpool's Data Archive. This data will be held indefinitely and will, to assist~~allow~~ other researchers to undertake future studies. Any information will be fully anonymised and can't be traced back to you.

What will happen to the results of this study?

The results will be written up as part of a masters thesis and will be published in an academic journal. A summary of the results, the thesis or any publications will be offered to each participant. If you are interested in receiving any results please inform the research team. Postage costs will be paid by the research team. It is important to note that you will not be identifiable in any publication.

Who has reviewed the study?

This study has been ethically approved by the Health Research Authority. It is audited and sponsored by the University of Liverpool's Joint Research Office.

Further information and contact details?

If you would like to discuss this study with anyone please do not hesitate to contact anyone below. A copy of the contact details are also on the first page of this information sheet. If you would like to find out more about research in healthcare please visit <http://www.hra.nhs.uk>. If you have any complaints, please do not hesitate to contact the people below.

Mr Joseph Alsousou (Principal Investigator)

T: 0151 706 4120

E: josephalsousou@doctors.org.uk

Trupesh Patel (Research Student)

T: 0151 706 4688

E: t.patel@liv.ac.uk

Ms Amanda Wood (Clinical Research Nurse)

T: 0151 706 4688

E: Amanda.wood@liverpool.ac.uk

Appendix G – Patient participant consent form

Please turn over.

Centre Number:

Study Number:

Participant Identification Number for this trial:

Study Title: Development and Validation of a Patient Reported Outcome Measure Assessing Lower Limb Joint Function

Consent Form 1 – Patient Participants.

Name of Researcher: Trupesh Patel

Please
initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by members of the research team and regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

☐

4. I agree to be audio recorded during the interview.

☐

5. I agree for my information to be submitted to the University of Liverpool's Data Archive and held indefinitely for future research.

☐

6. I agree to take part in this study

☐

Name of Participant

Date

Signature

Name of Person

Date

Signature

Appendix H – Patient participant consent form

Please turn over.

Baseline Assessment – Patient Participants

Participant number	
Age	
Sex	
Weight	
Height	
OA diagnosis?	
Duration of Symptoms	
Physical Activity Level (hours)	
Past Medical History	
Past treatment for OA.	

Appendix I – Interview Guide

- 1) Introduce myself and outline the purpose of the interview.
- 2) Establish verbal consent.
- 3) Re-check written consent.
- 4) Ask if participant has any questions.
- 5) Obtain baseline information. Inclusion/exclusion criteria.
- 6) Start Interview
 - a. Tell me about the effect osteoarthritis has had on your life?
 - i. If participant has difficulty in remembering details then probe for:
 1. Changing basic body position - Getting into and out of a body position and moving from one location to another, such as getting up out of a chair to lie down on a bed, and getting into and out of positions of kneeling or squatting.
 2. Maintaining a body position - Staying in the same body position as required, such as remaining seated or remaining standing for work or school
 3. Lifting or carrying objects - Raising up an object or taking something from one place to another, such as when lifting a cup or carrying a child from one room to another.
 4. Fine hand use - Performing the coordinated actions of handling objects, picking up, manipulating and releasing them using one's hand, fingers and thumb, such as required to lift coins off a table or turn a dial or knob.
 5. Hand and arm use - Performing the coordinated actions required to move objects or to manipulate them by using hands and arms, such as when turning door handles or throwing or catching an object.
 6. Walking - Moving along a surface on foot, step by step, so that one foot is always on the ground, such as when strolling, sauntering, walking forwards, backwards, or sideways
 7. moving around - Moving the whole body from one place to another by means other than walking, such as climbing over a rock or running down a street, skipping, scampering, jumping, somersaulting or running around obstacles.

8. **using transport** - Using transportation to move around as a passenger, such as being driven in a car or on a bus, rickshaw, jitney, animal-powered vehicle, or private or public taxi, bus, train, tram, subway, boat or aircraft.
9. **Driving** - Being in control of and moving a vehicle or the animal that draws it, travelling under one's own direction or having at one's disposal any form of transportation, such as a car, bicycle, boat or animal-powered vehicle.
10. **washing oneself** - appropriate cleaning and drying materials or methods, such as bathing, showering, washing hands and feet, face and hair, and drying with a towel.
11. **Toileting** - Planning and carrying out the elimination of human waste (menstruation, urination and defecation), and cleaning oneself afterwards.
12. **Dressing** - Carrying out the coordinated actions and tasks of putting on and taking off clothes and footwear in sequence and in keeping with climatic and social conditions, such as by putting on, adjusting and removing shirts, skirts, blouses, pants, undergarments, saris, kimono, tights, hats, gloves, coats, shoes, boots, sandals and slippers.
13. **acquisition of goods and services** - Selecting, procuring and transporting all goods and services required for daily living, such as selecting, procuring, transporting and storing food, drink, clothing, cleaning materials, fuel, household items, utensils, cooking ware, domestic appliances and tools; procuring utilities and other household services.
14. **doing housework** - Managing a household by cleaning the house, washing clothes, using household appliances, storing food and disposing of garbage, such as by sweeping, mopping, washing counters, walls and other surfaces; collecting and disposing of household garbage; tidying rooms, closets and drawers; collecting, washing, drying, folding and ironing clothes; cleaning footwear; using brooms, brushes and vacuum cleaners; using washing machines, driers and irons.

15. assisting others - Assisting household members and others with their learning, communicating, self-care, movement, within the house or outside; being concerned about the well-being of household members and others.
16. intimate relationship - Creating and maintaining close or romantic relationships between individuals, such as husband and wife, lovers or sexual partners
17. employment - Engaging in all aspects of work, as an occupation, trade, profession or other form of employment, for payment, as an employee, full or part time, or self-employed, such as seeking employment and getting a job, doing the required tasks of the job, attending work on time as required, supervising other workers or being supervised, and performing required tasks alone or in groups.
18. community life - Engaging in all aspects of community social life, such as engaging in charitable organizations, service clubs or professional social organizations.
19. recreation or leisure. Engaging in any form of play, recreational or leisure activity, such as informal or organized play and sports, programmes of physical fitness, relaxation, amusement or diversion, going to art galleries, museums, cinemas or theatres; engaging in crafts or hobbies, reading for enjoyment, playing musical instruments; sightseeing, tourism and travelling for pleasure.

b. What symptoms and/or other factors affect your ability to use your legs as you intend to (e.g. walking, standing up etc.)?

i. If participants have difficulty remembering details, then probe for

1. Products or substance for personal consumption - Any natural or human-made object or substance gathered, processed or manufactured for ingestion.
2. Products and technology for personal use in daily living - Equipment, products and technologies used by people in daily

activities, including those adapted or specially designed, located in, on or near the person using them.

3. Products and technology for personal indoor and outdoor mobility and transportation - Equipment, products and technologies used by people in activities of moving inside and outside buildings, including those adapted or specially designed, located in, on or near the person using them.
4. Design, construction and building products and technology of buildings for public use - Products and technology that constitute an individual's indoor and outdoor human-made environment that is planned, designed and constructed for public use, including those adapted or specially designed.
5. Design, construction and building products and technology of buildings for private use - Products and technology that constitute an individual's indoor and outdoor human-made environment that is planned, designed and constructed for private use, including those adapted or specially designed.
6. Climate - Meteorological features and events, such as the weather
7. Immediate family - Individuals related by birth, marriage or other relationship recognized by the culture as immediate family, such as spouses, partners, parents, siblings, children, foster parents, adoptive parents and grandparents.
8. Friends - Individuals who are close and ongoing participants in relationships characterized by trust and mutual support.
9. Personal care providers and personal assistants - Individuals who provide services as required to support individuals in their daily activities and maintenance of performance at work, education or other life situation, provided either through public or private funds, or else on a voluntary basis, such as providers of support for home-making and maintenance,

personal assistants, transport assistants, paid help, nannies and others who function as primary caregivers.

10. Health professionals - All service providers working within the context of the health system, such as doctors, nurses, physiotherapists, occupational therapists, speech therapists, audiologists, orthotist-prosthetists, medical social workers.
11. Individual attitudes of immediate family members - General or specific opinions and beliefs of immediate family members about the person or about other matters (e.g. social, political and economic issues), that influence individual behaviours and actions.
12. Individual attitudes of health professionals - General or specific opinions and beliefs of health professionals about the person or about other matters (e.g. social, political and economic issues), that influence individual behaviours and actions.
13. Societal attitudes - General or specific opinions and beliefs generally held by people of a culture, society, subcultural or other social group about other individuals or about other social, political and economic issues, that influence group or individual behaviour and actions.
14. Transportation services, systems and policies - Services, systems and policies for enabling people or goods to move or be moved from one location to another
15. General social support services and policies - Services, systems and policies aimed at providing support to those requiring assistance in areas such as shopping, housework, transport, self-care and care of others, in order to function more fully in society.
16. Health services, systems and policies - Services, systems and policies for preventing and treating health problems, providing medical rehabilitation and promoting a healthy lifestyle.

7) Thank participants for their co-operation and end interview.

Appendix J – Expert participants recruitment poster.

Please turn over.

Volunteers Needed for a Research Study

Are you an orthopaedic surgeon or
physiotherapist?

We would like to invite you to our study!

This research involves the development and validation of a new patient reported outcome measure that holistically assesses lower limb function in osteoarthritis. Your involvement will ensure that the questions selected for the outcome measure adequately assess functional capacity in osteoarthritis.

For more details, an information sheet can be requested via the information below.

Thankyou!

Trupesh Patel

(Intercalating medical student - MPhil Orthopaedic Biology. GCP Trained)

Email: t.patel@liv.ac.uk

Tel: 07794763419

Appendix K – Expert participants information sheet

Please turn over.

EXPERT PARTICIPANTS INFORMATION SHEET: DELPHI ANALYSIS

**Study Title: Development and Validation of a Patient
Reported Outcome Measure Assessing Lower Limb Joint
Function**

Contact information:

**Mr Joseph Alsousou (Principal
investigator)**

T: 0151 706 4120

E: josephalsousou@doctors.org.uk

Trupesh Patel (Research Student)

T: 0151 706 4688

E: t.patel@liv.ac.uk

**Ms Amanda Wood (Clinical
Research Nurse)**

T: 0151 706 4688

E: Amanda.wood@liverpool.ac.uk

Address:

Mr Alsousou or Trupesh Patel or
Amanda Wood,
Department of Molecular and Clinical
Cancer Medicine,
Royal Liverpool University Hospital,
Liverpool,
L69 3GA.

We would like to invite you to take part in a research study. Before you decide whether to take part, you need to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. This should take about 5 minutes of your time. If you have any questions do not hesitate to contact anyone listed at the end of this sheet.

Study Title

Development and validation of a patient reported outcome measure assessing lower limb joint function.

What is the purpose of this study?

Patient reported outcome measures are standardized questionnaires used to assess quality of life. They can be made up of several domains such as pain, sleep function and mobility. These questionnaires can be administered at a single point in time or longitudinally to assess any potential changes in health, due to treatment or progression of disease. Currently, several questionnaires are being used to assess mobility in patients with osteoarthritis of the hip, knee, foot or ankle. Although these are the best available, they do come with limitations, for example some patients may find the questions irrelevant, difficult to understand or may take too much of their time. This study aims to develop a new questionnaire that resolves some of these problems. We are inviting healthcare professionals who have experience caring for patients with osteoarthritis of the hip, knee, ankle or foot. The study will be performed at the Royal and Broadgreen University Hospital Trust.

Why have I been chosen?

You have been selected because you have expertise working with osteoarthritic patients and could help to create a new outcome measure.

What will happen if I choose to take part?

We would like to take the opportunity to inform you about the study. The study is divided into several stages that aim to create a new patient reported outcome measure. You are being invited to one of these stages. This part aims to reduce the number of questions by discarding those with poor content. If you agree to take part in this study you will be given a consent sheet to sign and return. Some baseline information will be taken: a) full job title (including grade if appropriate) b) years' experience caring for patients with osteoarthritis of the hip and/or knee and/or foot and/or ankle c) do you regularly use outcome measure in your practice d) qualifications. This part of the research will involve a Delphi analysis with 14 other orthopaedic surgeons, physiotherapists and nurses. The first round of the analysis will ask you to note down all the factors that would affect lower leg functional capacity in osteoarthritis. You will be required to email this list back to the research team. A compiled list of factors from all participants (including suggestions from osteoarthritic participants, as part of another study) will be emailed back to you. This will be in a questionnaire format and we will ask you to assess the quality of them. This will serve to reduce the amount of questions to a more manageable size by eliminating those questions that are not relevant. This is important as it validates the questionnaire with respect to its content. Due to the anonymous nature of the Delphi analysis, other participants will not know who the other fourteen are, nor their comments. This information will only be available to the research team. Each round will take around 15 minutes of your time. We can only inform you of the number of times you will be required to participate as the study goes along, but based on previous studies it may take 2-4 iterations. Time taken between rounds will be 2 weeks. This is give all participants ample time to return their response. All correspondence will be done via e-mail. This information will be securely stored and anonymized so that your personal details will NOT have any identifying information on it.

What are the advantages and disadvantages of taking part?

There is no direct benefit to participating in this research. Your data will remain anonymized for the entirety of the study. We do not anticipate any risks or harm towards you during our study.

What if something goes wrong?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. The principal investigator Joseph Alsousou can also be contacted on 0151 706 4120, clinical research nurse Amanda Wood on 0151 706 4688 or research student Trupesh Patel on 0151 706 4688.

What will happen if I don't want to carry on with the study?

Your decision to take part in this study is entirely voluntary; you can change your mind at any time. Should you wish to withdraw from the study, a member of the research team can be approached.

Will my information be kept confidential?

All information that is collected will be kept strictly confidential. Information collected from you will be anonymised and stored in secure storage. Identifiable information will be stored separately to the information you provide as part of the study. Storage is located at the University of Liverpool.

What will happen to my information after the study?

At the end of the study we will, with your consent, submit an anonymised data set containing your information to the University of Liverpool's Data Archive. This data will be held indefinitely and will assist other researchers to undertake future studies. Any information will be fully anonymised and can't be traced back to you.

What will happen to the results of this study?

The results will be written up as part of an MPhil thesis and will be published in an academic journal. A summary of the results, the thesis or any publications will be offered to each participant. If you are interested in receiving any results please inform the research team. Postage costs will be paid by the research team. It is important to note that you will not be identifiable in any publication.

Who has reviewed the study?

This study has been ethically approved by the Health Research Authority. It is audited and sponsored by the University of Liverpool's Joint Research Office.

Further information and contact details?

If you would like to discuss this study with anyone please do not hesitate to contact anyone below. A copy of the contact details are also on the first page of this information sheet. If you would like to find out more about research in healthcare please visit <http://www.hra.nhs.uk>. If you have any complaints, please do not hesitate to contact the people below.

Mr Joseph Alsousou (Principal Investigator)

T: 0151 706 4120

E: josephalsousou@doctors.org.uk

Trupesh Patel (Research Student)

T: 0151 706 4688

E: t.patel@liv.ac.uk

Ms Amanda Wood (Clinical Research Nurse)

T: 0151 706 4688

E: Amanda.wood@liverpool.ac.uk

Appendix L – Expert participant consent form

Please turn over.

Centre Number:

Study Number:

Participant Identification Number for this trial:

Study Title: Development and Validation of a Patient Reported Outcome Measure Assessing Lower Limb Joint Function

Consent Form 2 – Expert Participants

Name of Researcher: Trupesh Patel

Please
initial
box

7. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

☐

8. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

☐

9. I agree for my information to be submitted to the University of Liverpool's Data Archive and held indefinitely for future research.

☐

10. I agree to take part in this study

☐

Name of Participant

Date

Signature

Name of Person

Date

Signature

Appendix M – Baseline information collection sheet for expert participants.

Please turn over.

Baseline Assessment – Expert Participants

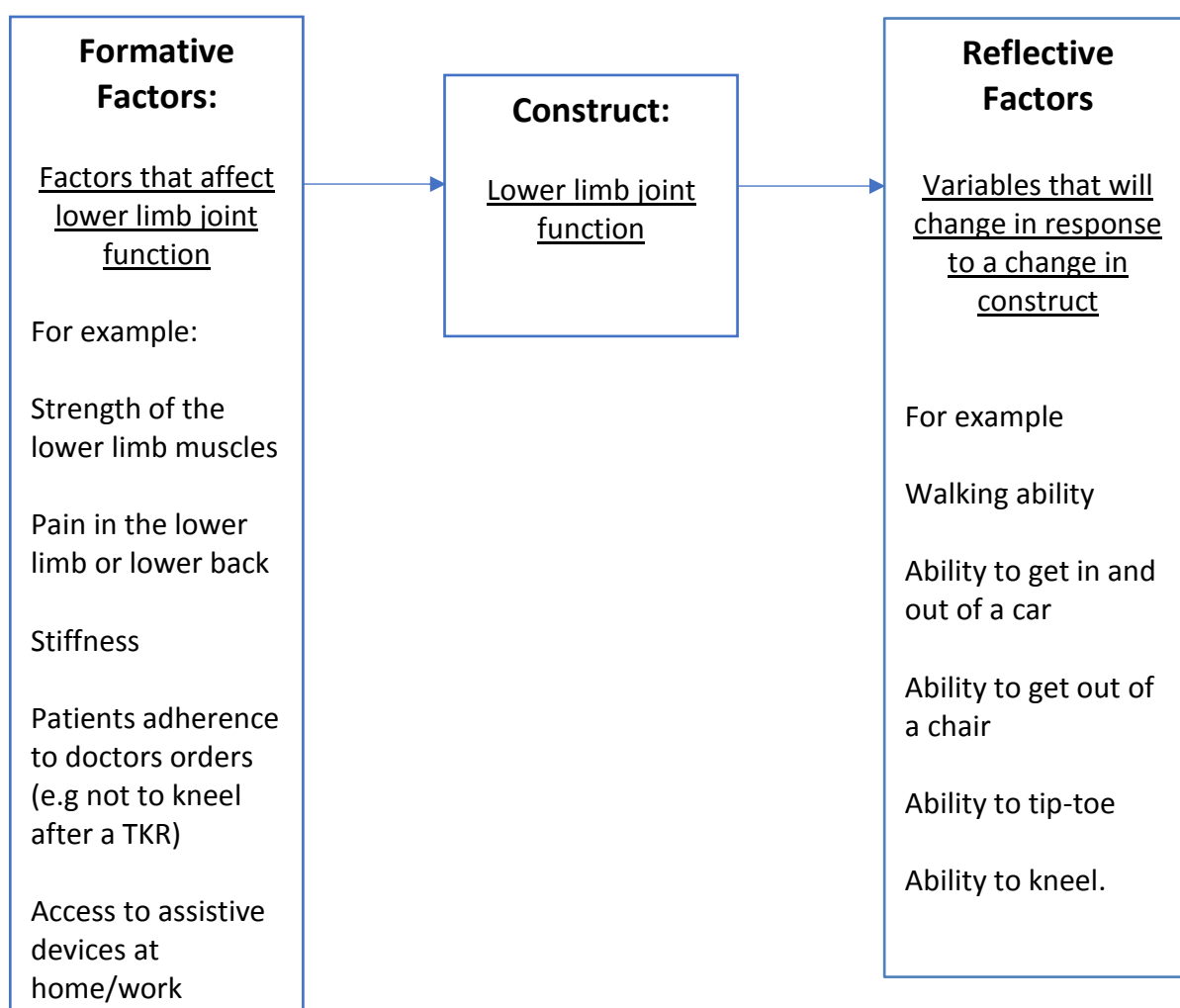
Participant number	
Job Title	
How many years' experience with patients with osteoarthritis of the hip and/or knee and/or foot and/or ankle	
Do you regularly use outcome measures in your practice?	
Qualifications	
Contact details.	(email -

Appendix N – Baseline information collection sheet for expert participants.

Please turn over.

Delphi Analysis Round 1

This is round 1 of the Delphi analysis. Before I ask you to complete the table on page 2, I would like to inform you of the conceptual model that I intend to base the outcome measure on. This will aid you in coming up with answers. This model is based on formative and reflective factors and their effect on a construct. A construct put simply is a phenomenon that exists. The construct being assessed in the novel outcome measure is the **lower limb joint function (mobility) of osteoarthritic patients**. Formative factors refer to variables that cause a change in the construct. Reflective factors are variables that will change if the construct changes. The model can be represented by the diagram below (including examples.)



I will be asking you to write down as many **factors that affect lower limb joint function (formative factors)** that can think off (you will NOT be required to write down any reflective factors). You do not need to write these as questions, simply write the concept. E.g do not write down “How much does your aerobic capacity affect your mobility?” instead just write down aerobic capacity. It is important that you think as **holistically as possible**.

Please write down as many formative factors you can think of i.e. what factors would affect a patient's lower limb joint function.

You can now e-mail this document back to *****@liv.ac.uk

The next Delphi stage will be emailed to you in due course. If you have any questions please do not hesitate to contact Trupesh Patel on [TELEPHONE AND EMAIL ADDRESS HAVE BEEN EDITED OUT]. Thankyou for your participation.

Appendix O – Patient Participant Raw Data (from interviews)

Patient Participant 1

Question 1 (reflective factor):

sports

bowling

walking

getting in and out of a car

putting on socks

Question 2 (formative factor):

Nil

Patient Participant 2

Question 1 (reflective factor):

walking home

walking to work

stair climbing

getting in and out of a car

Question 2 (formative factor):

my own effort to move around

Patient Participant 3

Question 1 (reflective factor):

getting up from the floor

doing dishes

walking

using stairs

get in and out of a bus

Question 2 (formative factor):

Nil

Patient Participant 4

Question 1 (reflective factor):

standing up

sitting up

walking around

sitting down

getting in and out of a bath

getting in and out of a car

Question 2 (formative factor):

copng mechanisms

use of aids

Patient Participant 5

Question 1 (reflective factor):

walking

bending over to pick something up

sitting down

standing idle for a period of time

going up and down stairs

sexual activities

hobbies

putting on footwear

showering

Question 2 (formative factor):

breathlessness

Patient Participant 6

Question 1 (reflective factor):

walking < 100 yards

kneeling down

in and out of a bath

cut vegetables

sports

climbing stairs

Question 2 (formative factor):

mood and willingness to get and move about

fear of injury

presence of a limp

Patient Participant 7

Question 1 (reflective factor):

gardening

walking

sitting in a chair

bathing

putting on socks

cutting toenails

getting in a car

Question 2 (formative factor):

oxygen problems and lung capacity

heart problems

Patient Participant 8

Question 1 (reflective factor):

walking up a hill

looking after my wife who's a wheelchair user
in and out of a shower
getting dressed

Question 2 (formative factor):

trust of joint moving as intended to
length of time moving
knowledge of whether moving more will make the joint worse
being aware that he has a problem

Patient Participant 9

Question 1 (reflective factor):

putting shoes on
putting socks on
cutting toenails
carrying objects in the hand
walking upstairs
sitting down
getting onto the floor/off the floor

Question 2 (formative factor):

ability to bend down
assistive devices
strength of the muscles

Patient Participant 10

Question 1 (reflective factor): =

walking
putting on shoes

Question 2 (formative factor):

backache
weight
breathlessness
mood
mental health
quality of shoes

Patient Participant 11

Question 1 (reflective factor):

kneeling down
sitting on the floor
rolling off bed to get up
standing up
bending down
walking

Question 2 (formative factor):

coping strategies
confidence while using sticks
balance
weight
pain
relying on wife to do activities (assistance)

Patient Participant 12

Question 1 (reflective factor):

walking
standing up

Question 2 (formative factor):

motivation

Patient Participant 13

Question 1 (reflective factor):

walking

Question 2 (formative factor):

their plantar fasciitis

Patient Participant 14

Question 1 (reflective factor):

sitting down

bathing

Question 2 (formative factor):

feeling of joint giving way

modifications at home

Patient Participant 15

Question 1 (reflective factor):

bending down to put on socks

Question 2 (formative factor):

NIL

Patient Participant 16

Question 1 (reflective factor):

standing up

dressing

going up stairs

walking

Question 2 (formative factor):

coping mechanisms

shower modification

general tiredness

Patient Participant 17

Question 1 (reflective factor):

housework

shopping

Holding objects in both hands for example holding a walking stick and umbrella.

walking

getting and out of a car/taxi

kneeling down

standing up from the floor/chair

sitting on a floor

Question 2 (formative factor):

low back pain

neck osteoarthritis

Patient Participant 18

Question 1 (reflective factor):

walking

climbing stairs

descending stairs

gardening

Question 2 (formative factor):

quality of public transportation

temperature – worse in the winter than summer.

coping mechanisms

OA in the hand

Patient Participant 19

Question 1 (reflective factor):

Walking down a steep hill

Walking generally

tennis

golf

standing up

Question 2 (formative factor):

limping

Patient Participant 20

Question 1 (reflective factor):

walking

putting on socks and shoes

dressing

getting in and out of a bath

climbing high steps

looking after grandson

Question 2 (formative factor):

stiffness

people watching me walk

Appendix I – Appendix Raw data patients 21-30

Patient Participant 21

Question 1 (reflective factor):

walking
biking
using stairs
getting in a car

Question 2 (formative factor):

depression (mood)
climates
personal motivation to move

Patient Participant 22

Question 1 (reflective factor):

walking
carrying bags
get in and out of a taxi
pushing a trolley (shopping)
getting on a bus

Question 2 (formative factor):

Nil

Patient Participant 23

Question 1 (reflective factor):

social activities like dancing
walking on trails and rough woods
getting in and out of a car
pushing trolleys
kneeling
standing up

Question 2 (formative factor):

fear of falling

work equipment available (foot rest)

quality of the lifts

Patient Participant 24

Question 1 (reflective factor):

washing herself

getting in a taxi

Question 2 (formative factor):

Nil

Patient Participant 25

Question 1 (reflective factor):

sports

walking

getting in and out of a chair

moving around generally

in and out of a car

Question 2 (formative factor):

upper body strength (getting out of a chair)

Patient Participant 26

Question 1 (reflective factor):

playing bowls

walking on cobbled surfaces

hovering

bending for dusting

getting in and out of a car

showering
kneeling down

Question 2 (formative factor):

strength in legs
giving way

Patient Participant 27

Question 1 (reflective factor):

Walking
Housework
Gardening
Getting in and out of bed
Getting in and out of car

Question 2 (formative factor):

Mood
Balance

Patient Participant 28

Question 1 (reflective factor):

fishing
standing up
putting on shoes and socks
cutting toenails

Question 2 (formative factor):

assistance at home
coping mechanisms
other people helping him

access to a commode

Patient Participant 29

Question 1 (reflective factor):

climbing stairs/descending
walking long periods of time
getting in and out of a car
showering

Question 2 (formative factor):

back pain
chest problems – breathlessness
age

Patient Participant 30

Question 1 (reflective factor):

climbing stairs
walking dog
getting in and out of a car
standing up and sitting
housework

Question 2 (formative factor):

Weight

Appendix P – Experts Participant Raw Data (from Delphi)

Expert Participant 1

- Local or generalised pain
- Impaired movement patterns
- Impaired neurological function
- Muscle weakness
- Altered spatial awareness, position perception e.g. vision, hearing, dementia, post CVA
- Personal beliefs and expectations e.g. more ambulation = more harm
- Beliefs of others (friends and family influences/ society influences)
- Media influences e.g. web sites
- Medication e.g. analgesia
- Attitude of healthcare professionals e.g. empathy, listening
- Concordance between healthcare professionals and individual
- Access to home adaptations e.g. shower, rails on stairs, stair lift
- Weather
- Walking aids e.g. stick, crutches, walking frame
- Social services support e.g. shopper, cleaner
- Social care benefits e.g. sick pay

Expert Participant 2

- Muscle Strength
- Proprioception / balance
- Pain and control of pain via analgesia
- Joint stiffness – actual or perceived
- Joint swelling
- Mechanical symptoms e.g. Locking, giving way, clicking, crepitus
- Ability to adhere to or access exercise
- Illness perception e.g. Avoidance of perceived detrimental activities
- Aids and braces – may either improve or restrict function

Expert Participant 3

- Pain at rest
- Difficulty with footwear
- Walking aids
- Swelling
- Deformity

Expert Participant 4

- Pain in lower limb
- Stiffness in lower limb
- Back pain or stiffness or deformity (e.g. scoliosis or kyphosis)
- Loss of movement due to Tendon rupture (e.g. Achilles or quadriceps or ACL)
- Instability of joint (e.g. ankle or knee giving way)
- Leg length difference
- Balance problems
- Weakness of lower limb (e.g. after stroke or foot drop or polio)
- (inappropriate) Type Shoe wear (e.g. high heels)
- Respiratory and cardiac function
- Loss of sensation (foot numbness 2ndry to nerve injury or peripheral neuropathy)
- Weight (obesity)
- Deformity (e.g. flat foot, malunion fracture long bone- femur or tibia)
- Absent or short limb on opposite side – amputation or congenital

Expert Participant 5

- sense of Balance
- strength in LL muscles individually
- Strength in the LL as a whole egg Squat/small knee bend/calf raise/
ascend/descend against gravity
- stiffness
- ROM of knee and joint above and below

- pain scale

Expert Participant 6

- Stiffness
- Fixed deformity
- Cardiac or respiratory problems
- Quadriceps strength
- Patients understanding of the procedure and post-op protocol
- Patient expectations of mobility
- Hip pain
- Low back pain

Expert Participant 7

- Pain in lower limbs
- Pain on lumbar spine
- Stiffness in lower limbs or spine
- Strength of muscles
- Oedema in lower limb
- Circulatory problems- swelling, ulcers, claudication reducing exercise tolerance.
- Co-morbidities which affect exercise tolerance e.g. angina (not able to exercise therefore weakened muscles and stiff joints)
- Neurological conditions affecting muscle strength or co-ordination e.g. Parkinson's/ CVA
- Cognitive impairment affecting understanding of need to exercise/move joints.
- Balance
- Patients ability to follow medical advice regarding range of movement and exercise
- Access to equipment to aid rehabilitation e.g. walking aids, gym or swimming pool

Expert Participant 8

- Pain
- Muscle strength

- Muscle co-ordination
- Personality traits and social circumstances (employed)
- Patient experience during hospital stay

Expert Participant 9

- Joint stability
- Joint alignment
- Muscle power
- Muscle tone
- Perfusion
- Pain and swelling

Expert Participant 10

- Pain with ambulation
- Stability of the knee and ankle
- Stiffness of hip and knee
- Muscle power
- Mood / depression – subjective function only
- Previous trauma, number of previous lower limb surgeries
- Social support i.e. supportive partner or family
- Pre-op analgesic requirement (lower = less post-op function)
- Number of reported allergies (inversely proportional to subjective function)
- Age at onset of symptoms
- Radiographic severity of osteoarthritic disease

Expert Participant 11

- Patient factors
 - Motivation
 - Personality
 - Family support
 - Home circumstances

- Pain tolerance
- Pre-habilitation
 - Joint school
 - Physiotherapy
 - Knowing what to expect
- Operative/Rehab factors
 - Implant positioning
 - Pre-op level of function and steps to correct e.g. posterior release in TKR etc.)
 - Rehab pathway

Appendix Q - Formative factors initial codes

Products and technology for personal use in daily living

Use of a walking aid

Walking aids e.g. stick crutches, walking frame

Aids or braces

Modifications at home like stair assist and railing near the bath

Shower modifications

Access to home adaptations like shower, rails on stairs, stair lift

Quality of shoes

Difficulty with footwear

Inappropriate footwear

Products and technology for employment

Work equipment availability like foot rest

Design, construction and building products and technology of buildings for public use

Access to equipment to aid rehabilitation e.g. walking aids, gym or swimming pool

Climate

Weather

Immediate family

Relying on wife to do activities (assistance)

Personal care providers and personal assistants

Other people helping him; cleaner.

Social services support e.g. shopper, cleaner

Health professionals

Knowledge of whether moving more will make the joint worse

Concordance between healthcare professional and individuals

Patients understanding of procedure and the post op protocol

Radiographic severity of osteoarthritic disease

Implant positioning

Pre-op level of function and steps to correct e.g. posterior release in TKR

Cognitive impairment affecting the understanding of need to exercise/move joints

Individual attitudes of immediate family members

Beliefs of others (friends and family influences/societal influences)

Social support i.e. supportive partner or family

Family support

Home circumstances

Individual attitudes of health professionals

Attitude of healthcare professionals e.g. empathy, listening

Transportation services, systems and policies

Quality of the public transportation – if the buses can lower themselves etc.

General social support services, systems and policies

Patient experience during hospital stay

Physiotherapy access

Media influences e.g. websites

UNCODED RESPONSES:

Limp

Limping

Limping

Strength of my leg muscles

Strength in legs
Muscle weakness
Strength in LL muscles (as a whole)
Strength in LL muscles individually
Quadriceps strength
Strength of lower limb muscles
Muscle power
Muscle power
Muscle co-ordination
Muscle tone
Muscle strength
Pain
Local or generalised pain
Pain at rest
Pain in the lower limb
Pain
Pain
Pain with ambulation
Pain (and swelling)
Pain or stiffness in lower limbs
Medication e.g. analgesia
Pain and control of pain via analgesia
Pain tolerance
Feeling of joint giving way
Giving way
Instability in the joint (ankle or knee giving way)
Joint stability
Joint alignment
Stability of the knee and ankle
Mechanical symptoms e.g. locking, giving way, clicking, crepitus
Stiffness
Stiffness in the lower limb

Stiffness
Stiffness
Stiffness in lower limbs
Stiffness of the hip and knee
Joint stiffness actual or perceived
Swelling
Swelling in lower limb
Joint swelling
Deformity
Fixed deformity
LL discrepancy
Leg length difference
Walking aids
Perfusion
Age at onset of symptoms
Breathlessness
Oxygen problems and lung capacity on account of my COPD
Breathlessness
Breathlessness
Cardiac or respiratory problems
Co-morbidities which affect exercise tolerance e.g. angina
Respiratory and cardiac function
Mood
Mood/mental health
Depression
Mood
Mood/depression
Heart problems
Circulatory problems e.g. swelling, ulcers, claudication reducing exercise tolerance
Backache
Back pain
Low back pain

Low back pain
 Range of movement in joint above or below
 Plantar fasciitis
 Neck OA
 Hand OA
 Deformity (e.g. flat foot, malunion after fracture long bone- femur or tibia)
 Upper body strength
 Back pain or stiffness or deformity (e.g. scoliosis or kyphosis)
 Loss of movement due to tendon rupture e.g. Achilles or quadriceps or ACL
 Absent or short limb on opposite side – amputation or congenital
 Previous trauma, number of previous lower limb surgeries
 Weight
 Weight
 Weight
 Balance
 Balance
 Balance
 Balance problems
 Proprioception/balance
 Proprioception
 Sense of balance on affected leg
 General tiredness
 Number of reported allergies (inversely proportional to subjective function)
 Impaired neurological function
 Altered spatial awareness, position perception e.g. vision, hearing dementia, post CVA
 Loss of sensation (foot numbness 2ndry to nerve injury or peripheral neuropathy)
 Weakness of lower limb (e.g. after stroke or polio)
 Neurological conditions affecting muscle strength of co-ordination e.g. Parkinson
 Fear of an injury
 Trusting the joint to move as it intends to
 Knowledge of whether moving the joint more will make the joint worse
 Confidence while using sticks

Fear of falling

Fear and avoidance of moving due to pain

People watching me walk is embarrassing

My own effort to move around

Willingness to move about

Motivation to go for a walk

Motivation

Personal beliefs and expectation e.g. more ambulation = more harm

Social circumstances e.g. being employed

Personality

Adapt to situations like walking upstairs, backwards

Coping mechanisms

Learn to live with it, bought another car that is higher.

Appendix R - Formative Factors all coded

Limp

Limp

Limping

Limping

Pain

Pain

Local or generalised pain

Pain at rest

Pain in the lower limb

Pain

Pain

Pain with ambulation

Pain (and swelling)

Pain or stiffness in lower limbs

Pain control

Medication e.g. analgesia

Pain and control of pain via analgesia

Pain tolerance

Mechanical symptoms

Feeling of joint giving way

Giving way

Instability in the joint (ankle or knee giving way)

Joint stability

Joint alignment

Stability of the knee and ankle

Mechanical symptoms e.g. locking, giving way, clicking, crepitus

Stiffness

Stiffness

Stiffness in the lower limb

Stiffness

Stiffness

Stiffness in lower limbs

Stiffness of the hip and knee

Joint stiffness actual or perceived

Swellings

Swelling

Swelling in lower limb

Joint swelling

Deformity

Deformity

Fixed deformity

LL discrepancy

Leg length difference

MISC

Walking aids

Perfusion

Age at onset of symptoms

Co-morbidities

Pulmonary

Breathlessness

Oxygen problems and lung capacity on account of my COPD

Breathlessness

Breathlessness

Cardiac or respiratory problems

Co-morbidities which affect exercise tolerance e.g. angina

Respiratory and cardiac function

Psychiatric

Mood

Mood/mental health

Depression

Mood

Mood/depression

Cardiac

Heart problems

Circulatory problems e.g. swelling, ulcers, claudication reducing exercise tolerance

Musculoskeletal

Backache

Back pain

Low back pain

Low back pain

Range of movement in joint above or below

Plantar fasciitis

Neck OA

Hand OA

Deformity (e.g. flat foot, malunion after fracture long bone- femur or tibia

Upper body strength

Back pain or stiffness or deformity (e.g. scoliosis or kyphosis)

Loss of movement due to tendon rupture e.g. Achilles or quadriceps or ACL

Absent or short limb on opposite side – amputation or congenital

Previous trauma, number of previous lower limb surgeries

Strength of my leg muscles

Strength in legs

Muscle weakness

Strength in LL muscles (as a whole)

Strength in LL muscles individually

Quadriceps strength

Strength of lower limb muscles

Muscle power

Muscle power

Muscle co-ordination

Muscle tone

Muscle strength

General health issues

Weight

Weight

Weight

Balance

Balance

Balance

Balance problems

Proprioception/balance

Proprioception

Sense of balance on affected leg

General tiredness

Number of reported allergies (inversely proportional to subjective function)

Neurological

Impaired neurological function

Altered spatial awareness, position perception e.g. vision, hearing dementia, post CVA

Loss of sensation (foot numbness 2ndry to nerve injury or peripheral neuropathy

Weakness of lower limb (e.g. after stroke or polio)

Neurological conditions affecting muscle strength of co-ordination e.g. Parkinson

Individual attitudes/behaviours

Fear

Fear of an injury

Trusting the joint to move as it intends to

Knowledge of whether moving the joint more will make the joint worse

Confidence while using sticks

Fear of falling

Fear and avoidance of moving due to pain

People watching me walk is embarrassing

Motivation

My own effort to move around

Willingness to move about

Motivation to go for a walk

Motivation

Others

Personal beliefs and expectation e.g. more ambulation = more harm

Social circumstances e.g. being employed

Personality

Coping strategies

Adapt to situations like walking upstairs, backwards

Coping mechanisms

Learn to live with it, bought another car that is higher.

APPENDIX S - Reflective Factors Codes Initial and final

Changing basic body position

Kneeling down

Kneeling down

Kneeling down

Kneeling down

Kneeling down

Kneeling down

Sitting in a chair

Sitting down

Sitting down

Sitting down

Sitting down

Getting in and out of a chair

Standing up and sitting

Sitting in a chair

Standing up

Standing up

Standing up

Standing up

Standing up

Standing up

Standing up

Standing

Sitting on the floor

Sitting on the floor

Sitting on a floor

Getting up from the floor

Standing up from the floor/chair

Getting onto the floor/ off the floor

Getting up from the floor

Rolling off bed to get up

Getting out of bed

Bending over to pick something up

Bending down

Maintaining a body position

Standing idle for a period of time

Lifting and carrying objects

Carrying objects in the hand

Carrying bags

Fine hand use

Cutting vegetables

Cutting toenails

Cutting toenails

Cutting toenails

Hand and arm use

Holding objects in both hands for example holding a walking stick and umbrella.

Pushing a trolley

Pushing a trolley

Walking

General walking

Walking

Walking

Walking around

Walking

Walking <100yards

Walking

Walking

Walking
Walking
Walking
Walking
Walking
Walking
Walking
Walking generally
Walking
Walking
Walking
Walking
Walking
Walking
Walking for long periods of time
Walking home
Walking to work

Moving around

Walking up a hill
Walking down a steep hill
Walking on trails and rough woods
Walking on cobbled surfaces
Stair climbing
Using stairs
Going up and downstairs
Getting up and getting downstairs
Going upstairs
Climbing stairs
Descending stairs
Climbing stairs
Using stairs

Climbing stairs

Climbing stairs/descending stairs

Climbing high steps

Moving around generally

Using transportation

Getting in and out of a car

Getting in and out of a car

Getting in and out of a bus

Getting in and out of a car

Getting in a car

Getting in and out of a car

Getting in a car

In and out of a car

Getting in and out of a car

Getting out of the car

Getting in and out of a car

Getting in and out of a car

Getting in and out of a car

Getting on a bus

Getting out of a taxi

Getting in and out of a taxi

Getting in a taxi

Washing oneself

Washing herself

Getting in and out of a bath

In and out of a bath

Bathing

Bathing

Getting in and out of a bath

Showering

Getting in and out of a shower

Showering

Showering

Dressing

General

Dressing

Dressing

Getting dressed

Putting on socks

Putting on footwear

Putting on socks

Putting shoes on

Putting socks on

Putting on shoes

Bending down to put on socks

Putting on socks and shoes

Putting on shoes and socks

Doing housework

Doing the dishes

Housework

Hoovering

Bending down for dusting

Housework

Housework

Assisting others

Looking after my wife who's a wheelchair user

Looking after grandson

Intimate relationships

Sexual activities

Recreation and leisure

Sports

Bowling

Hobbies

Sports

Gardening

Shopping

Gardening

Tennis

Golf

Biking

Social activities like dancing

Sports

Playing bowls

Gardening

Fishing

Walking the dog